

US3302383 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:00:55

All time stamps listed in this document are displayed in GMT

US3302383

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:35:30

Generated On: 09 Jun 2021 17:00:55

---

[Participant ID](#)

US3302383

---

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

---

---

US3302383

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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

Visit date (dd MMM yyyy)	26 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
------------	------

US3302383

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	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

US3302383

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3302383

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3302383

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3302383

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Condition	TOURETTE'S SYNDROME
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



US3302383

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3302383

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:19 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:19
Height ( <i>xxx.x</i> )	68 in
Weight ( <i>xxx.x</i> )	200 lb
BMI ( <i>xxx.x</i> )	30.47348 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302383

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3302383

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3302383

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

<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>	

US3302383

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108672

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 ☒



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Height	ND - Not Done
Weight	ND - Not Done

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:19
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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)	26 AUG 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:16
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3302383

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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.*

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 11:46 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:46

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

US3302383

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	11:26 (24 HR)
Collection date and time (derived)	26 AUG 2020 11:26

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	26 AUG 2020 11:24
Nasopharyngeal Swab 2	No		

US3302383

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**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

96.8 °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

26 AUG 2020 12:06

PC Open Date & Time

26 AUG 2020 12:06

PC Close Date & Time

26 AUG 2020 14:36

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**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	27 AUG 2020 06:57
PC Open Date & Time	26 AUG 2020 15:31
PC Close Date & Time	27 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**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

29 AUG 2020 17:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**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

96.8 °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

30 AUG 2020 17:27

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 09:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 14:11

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**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

26 AUG 2020 12:07

PC Open Date & Time

26 AUG 2020 12:06

PC Close Date & Time

26 AUG 2020 14:36

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**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

27 AUG 2020 06:57

PC Open Date & Time

26 AUG 2020 15:31

PC Close Date & Time

27 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**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

27 AUG 2020 12:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**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

28 AUG 2020 12:04

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**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

29 AUG 2020 17:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**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

30 AUG 2020 17:27

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**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

01 SEP 2020 09:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**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

01 SEP 2020 14:11

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**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 ☐

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 12:07
PC Open Date & Time	26 AUG 2020 12:06
PC Close Date & Time	26 AUG 2020 14:36

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**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 ☐

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 06:58
PC Open Date & Time	26 AUG 2020 15:31
PC Close Date & Time	27 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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 ☒

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

46 of 1921

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:04
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**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 ☒

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 17:08
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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 ☒

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:27
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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 ☒

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 09:54
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

54 of 1921

EAB) (1725)

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 14:11
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59



US3302383

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302383

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

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*

US3302383

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302383

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3302383

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

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

SUBJECT COMPLETING  
CONVULSANT PHASE

*If Contact Not Made, please provide Comments*



US3302383

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

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

PT IS IN CONVULSANT PHASE

*If Contact Not Made, please provide Comments*

US3302383

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302383

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302383

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:33

Generated On: 09 Jun 2021 17:00:55

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

28 OCT 2020 10:26:01

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

03 NOV 2020 12:04:33

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59



US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 NOV 2020 17:07:02
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 06:30:21
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

04 DEC 2020 08:38:57

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 08:04:03

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 05:24:30

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 06:52:23
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 00:02:35

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

09 JAN 2021 20:07:42

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59



US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 19:24:57

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

22 JAN 2021 07:18:01

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**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

29 JAN 2021 10:39:56

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 06:51:49

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

**US3302383**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 17:00:55**

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

Date of Contact	22 SEP 2020
Time of Contact	17:13
Date and Time of Contact (derived)	22 SEP 2020 17:13
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		88 of 1921
EAB) (1725)		

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

96 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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)

97 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

100 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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)

101 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

104 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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)

105 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

124 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

128 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

129 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

132 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

136 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

141 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

	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	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

144 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

145 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

Date of Visit	22 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	22 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

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 \_\_\_\_\_

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

149 of 1921

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



US3302383

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 SEP 2020
Day 5	Yes	26 SEP 2020
Day 7	No	
Day 9	No	
Day 14	Yes	05 OCT 2020
Day 21	No	
Day 28	Yes	19 OCT 2020

US3302383

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

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	SICKD1

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

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)	13:27 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 13:27
Height (xxx.x)	172.7 cm
Weight (xxx.x)	198 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302383

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

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.*

US3302383

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 SEP 2020

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

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	SICKD28

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

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)	08:21 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:21
Height (xxx.x)	68 in
Weight (xxx.x)	195 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

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.*



US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Mar 2021 21:44:48

Generated On: 09 Jun 2021 17:00:55

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

**US3302383**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

Was this visit performed? Yes ☐  
No ☐

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

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

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

US3302383

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

Form: Unblinding

Generated On: 09 Jun 2021 17:00:55

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3302383

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:55

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

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

**US3302383**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:00:55**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00 - 23:59</i> )	<hr/>
Collection Date and Time (derived)	<hr/>

US3302383

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Oct 2020 21:44:42

Generated On: 09 Jun 2021 17:00:55

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

AEID	USA-US087-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE RESPIRATORY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	28 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

166 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input 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	



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

---

SUBJECT WAS CONTACTED TODAY FOR DAY 7 AND HE REPORTED THAT HE WAS ADMITTED TO THE HOSPITAL ON 9/26/2020. HE STATED THAT HIS PREVIOUSLY REPORTED SYMPTOMS HAVE GOTTEN BETTER. HE WENT TO THE HOSPITAL DUE TO HIS OXYGEN LEVEL BEING LOW ON 9/26/2020. SUBJECT CONFIRMED WITH ME VIA PHONE THAT HE WAS DIAGNOSED WITH PNEUMONIA. MEDICAL RECORDS TO BE REQUESTED ONCE SUBJECT IS DISCHARGED FROM HOSPITAL AND IS ABLE TO COME TO SITE TO SIGN RECORD RELEASE FORM. UPDATES WILL BE MADE AS RECORDS ARE RECEIVED AND REVIEWED. UPDATE: 10/1/2020 SUBJECT REPORTED THAT HE WAS DISCHARGED ON EVENING OF 9/28/2020. RECORDS RELEASE FORM HAS NOW BEEN SIGNED BY SUBJECT AND RECORDS HAVE BEEN REQUESTED TO CONFIRM ALL INFORMATION FROM HOSPITALIZATION. MEDICAL RECORDS WERE RECEIVED AND REVIEWED 10/15/2020. SUBJECTS DISCHARGE DIAGNOSIS NOTES

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

---

THE PRINCIPAL PROBLEM WAS ACUTE RESPIRATORY FAILURE WITH HYPOXIA WITH ACTIVE PROBLEMS OF HYPERLIPIDEMIA, PNEUMONIA DUE TO COVID-19 AND TIC DISORDER. SUBJECT PRESENTED TO ER WITH ACUTE SHORTNESS OF BREATH, FOUND TO BE HYPOXIC REQUIRING 3L OXYGEN BY NASAL CANNULA. PATIENT WAS AFEBRILE AND TACHYCARDIC ON ARRIVAL, SATTING 89% ON ROOM AIR, IMPROVED ON SUPPLEMENTAL OXYGEN. HE WAS CONSENT FOR TREATMENT WITH REMDESIVIR AND COVALESCENT PLASMA. HE RECEIVED 2 DAYS OF REMDESIVIR 9/26-9/27 AND RECEIVED CONVALESCENT PLASMA ON 9/26. A CHEST X-RAY WAS DONE 9/26/2020 SHOWING BILATERAL INFILTRATES CONSISTENT WITH INFECTION. PER RECORDS SUBJECT IS TO START MICINEX BID, TESSALON PRN, ALBUTEROL QID, DECADRON, VITAMIN C, THIAMINE AND ZINC AND SUPPLEMENTAL OXYGEN. LIPITOR IS TO BE TAKEN 40MG

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

---

NIGHTLY. KLONOPIN WAS  
PRESCRIBED TID PRN. SUBJECT  
WAS DISCHARGED 9/28/2020  
AND WAS ABLE TO BE  
WEANED DOWN TO ROOM AIR  
WITH SATURATIONS IN THE  
HIGH 90S.

---

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

---

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

AEID	USA-US087-2020-MRNA-1273-P30 1000001
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)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

171 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input 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	
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)	

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

AEID

Adverse event

WORSENING HYPERLIPIDEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

173 of 1921

EAB) (1725)

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

AEID

Adverse event

PNEUMONIA (DUE TO  
COVID-19)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☒

No ☐

Start date (dd MMM yyyy)

22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

175 of 1921



US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 16:04:43

Generated On: 09 Jun 2021 17:00:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

---

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

Yes ☒

No ☐

---

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

---

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication CITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication TOURETTE'S SYNDROME

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)

178 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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 2008	
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"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication MONTELAUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

180 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication TOURETTE'S SYNDROME

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

182 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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 2008
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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)

184 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication REMDESIVIR

Prophylaxis Yes ☐  
No ☒

Indication SAE - ACUTE RESPIRATORY FAILURE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

186 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 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"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1200

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)

188 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 OCT 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"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication TESSALON

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

190 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 90

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)

192 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

194 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication THIAMINE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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)

196 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication LIPITOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

198 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication ZINC

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

200 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication DECADRON

Prophylaxis Yes ☐  
No ☒

Indication AE - ACUTE RESPIRATORY FAILURE

Dose per administration 0.75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

202 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

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

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

Name of Medication OXYGEN

Prophylaxis Yes ☐  
No ☒

Indication AE (ACUTE RESPIRATORY FAILURE)

Dose per administration 3

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

If dose unit is Other, specify L/MIN

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 ☐

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 16:04:44

Generated On: 09 Jun 2021 17:00:55

	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)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 19:35:31

Generated On: 09 Jun 2021 17:00:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 SEP 2020	CONVALESCENT PLASMA	Adverse Event	
26 SEP 2020	CHEST X-RAY	Adverse Event	



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

### Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

End of Study / Study Discontinuation	False
All	True
Date of missed or out of window visit or assessment	24 SEP 2020
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
<b>Description of Relationship to COVID-19</b>	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	True
Participant decision	False

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input checked="" type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

**Case Report Form**

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

End of Study / Study Discontinuation	False
All	True
Date of missed or out of window visit or assessment	19 OCT 2020
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
<b>Description of Relationship to COVID-19</b>	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	True
Participant decision	False

US3302383

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

Date of dosing discontinuation (dd MMM yyyy) 29 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 25 Mar 2021 18:23:15

Generated On: 09 Jun 2021 17:00:55

Date of study discontinuation/completion (dd MMM yyyy) 19 OCT 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

SUBJECT WITH DREW  
CONSENT AFTER COMPLETING  
ILLNESS VISITS.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

\_\_\_\_\_

\_\_\_\_\_

Date of death (dd MMM yyyy)

\_\_\_\_\_

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:40
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



US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	01/OCT/2020 12:56
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

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/OCT/2020 13:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/OCT/2020 13:16
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.	True

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/NOV/2020 11:32
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

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/NOV/2020 09:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 19:35:32

Generated On: 09 Jun 2021 17:00:55

SAEID	USA-US087-2020-MRNA-1273-P301000001
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 18:27
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

US3302383 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

**US3302383**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:00:55**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'US3302383'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:18:22



**US3302383**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:00:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:49:33

US3302383

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:18:23

US3302383

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:49:33

**US3302383**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'SCRN'	System	26 Aug 2020 15:49:33

US3302383

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:18:25

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '54'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'YEARS'	System	26 Aug 2020 15:49:45



**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '54'	System	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered 'Male (M)'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

US3302383

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered 'l'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45



**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

US3302383

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

**US3302383**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:00:55**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:06
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:45

US3302383

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:55**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'Aug 2020'	System	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:55**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '2020'	System	26 Aug 2020 15:49:53

US3302383

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 14:55:27
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53



US3302383

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:55

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:55**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53

US3302383

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:55**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:49:53

**US3302383**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:00:55**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:26
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:18:23

US3302383

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'I'	System	26 Aug 2020 15:50:00

US3302383

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:00:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:50:54
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:50:00

US3302383

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:00:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:50:12



US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Neurological disorders congenital, HLT: Neurological disorders congenital NEC, PT: Tourette's disorder, LLT: Tourette's syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:50
Data point term sent to Coder	System	26 Aug 2020 15:51:43
User entered 'tourette's syndrome'	Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'un UNK 2008'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:02

**US3302383**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'Jan 2008'	System	26 Aug 2020 15:51:02

**US3302383**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '2008'	System	26 Aug 2020 15:51:02



**US3302383**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:02

**US3302383**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:02

US3302383

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:49
Data point term sent to Coder	System	26 Aug 2020 15:51:43
User entered 'hyperlipidemia'	Brittany Belcher (b) (4)	26 Aug 2020 15:51:14

US3302383

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'un UNK 2015'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:14

US3302383

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:14

**US3302383**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:14

US3302383

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:14

US3302383

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:14



**US3302383**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'Jan 2015'	System	26 Aug 2020 15:51:14

**US3302383**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '2015'	System	26 Aug 2020 15:51:14

**US3302383**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:14

**US3302383**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:14

US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:52:50
Data point term sent to Coder	System	26 Aug 2020 15:51:44
User entered 'seasonal allergies'	Brittany Belcher (b) (4)	26 Aug 2020 15:51:27

US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'un UNK 2000'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:27

US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:27

**US3302383**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:27



US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:27

US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:51:27

**US3302383**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'Jan 2000'	System	26 Aug 2020 15:51:27

US3302383

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '2000'	System	26 Aug 2020 15:51:27

**US3302383**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:27

**US3302383**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	26 Aug 2020 15:51:27

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00



**US3302383**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered '11:19'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

**US3302383**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 11:19'	System	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered '68' in	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00
DataPoint set to visible.	System	26 Aug 2020 15:50:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered '200' lb	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00
DataPoint set to visible.	System	26 Aug 2020 15:50:00

**US3302383**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
Amendment Manager: User entered '30.47348'	System	17 Sep 2020 00:03:35
User entered '30.5'	System	26 Aug 2020 15:52:00
DataPoint set to visible.	System	26 Aug 2020 15:50:00

**US3302383**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'kg/m2'	System	26 Aug 2020 15:52:00
DataPoint set to visible.	System	26 Aug 2020 15:50:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:25:56
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 18:54:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:15:42
User entered '96.8' F	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00



US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User entered '68'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

**US3302383**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'bpm'	System	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User entered '16'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'breaths/min'	System	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User entered '126'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:54:37
User entered '81'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:00



US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	26 Aug 2020 15:52:00

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13

US3302383

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13

US3302383

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:52:06

US3302383

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:52:06

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27



US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27



US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 19:10:25
User entered '1'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

**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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:27:21
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:53:14
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 19:10:25
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27



US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:52:52
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:52:27

US3302383

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 2 Day 29 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 2 Day 29 Visit on Immunogenicity Assessment page.' answered with '19OCT2020 is from the day 28 illness visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 06:22:13
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 2 Day 29 Visit on Immunogenicity Assessment page.' (Site from DM). User entered 'Yes (Y)'	Wendy Taylor (b) (4)	23 Dec 2020 12:29:25
	(b) (4), (b) (6)	22 Dec 2020 10:23:23
	Brittany Belcher (b) (4)	26 Aug 2020 15:54:59

US3302383

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Reconciliation: Swab sample for Visit3 Day57 has been received by Central Lab with date 19Oct2020. However Visit 2 and Visit 3 have not been filled out please confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:08:29
Query 'Per GCL Lab Reconciliation: Swab sample for Visit3 Day57 has been received by Central Lab with date 19Oct2020. However Visit 2 and Visit 3 have not been filled out please confirm and update accordingly.' answered with 'visit 2 and visit 3 were not done' (Site from DM).	brittany cooksey (b) (4)	10 Nov 2020 22:18:27
User opened query 'Per GCL Lab Reconciliation: Swab sample for Visit3 Day57 has been received by Central Lab with date 19Oct2020. However Visit 2 and Visit 3 have not been filled out please confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:35:08
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:59

US3302383

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 15:54:59

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'VISIT1'	System	26 Aug 2020 15:54:59

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:40:17

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered '108672'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:40:17



US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:40:17

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:11

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:11

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:11

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:11

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:11

US3302383

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:55

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:08
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 13:45:36
DataPoint set to visible.	System	23 Oct 2020 14:55:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:02:18

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:38
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:53:41
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 18:55:26
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:15:49
User entered '68' in	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered '200' lb	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:38
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:53:41
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 18:55:26
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:15:49
User entered '68' in	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered '200' lb	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '26 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '11:19' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 11:19'	System	07 Oct 2020 18:55:23
User entered empty.	System	26 Aug 2020 17:20:23



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '96.8' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '68' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'bpm'	System	07 Oct 2020 18:55:23
User entered empty.	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '16' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'breaths/min'	System	07 Oct 2020 18:55:23
User entered empty.	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '126' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	07 Oct 2020 18:55:23
User entered empty.	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '81' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	07 Oct 2020 18:55:23
User entered empty.	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:38
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:53:41
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 18:55:26
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:15:49
User entered '68' in	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 18:55:23
User entered '200' lb	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '12:16'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 12:16'	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '96.8' F	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '65'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'bpm'	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '18'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23



US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'breaths/min'	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '121'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:25:32
User entered '78'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'mmHg'	System	26 Aug 2020 17:20:23

US3302383

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:34

US3302383

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	26 Aug 2020 17:20:34

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24



US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

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 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered '26 Aug 2020'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered '11:46'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 11:46'	System	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:56
User entered 'ONCE'	System	26 Aug 2020 15:55:24



US3302383

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:55:24

US3302383

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:45

US3302383

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:45

US3302383

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '11:26'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:45

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:00:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 11:26'	System	26 Aug 2020 17:20:45

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:57



US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '11:24'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '26 Aug 2020 11:24'	System	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Wendy Taylor (b) (4)	20 Oct 2020 18:30:11
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty; reason for change Data Entry Error	(b) (4) Wendy Taylor (b) (4)	20 Oct 2020 18:30:11
User entered '11:24'	Brittany Belcher (b) (4)	26 Aug 2020 17:20:57

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered empty.	System	20 Oct 2020 18:30:11
User entered '26 Aug 2020 11:24'	System	26 Aug 2020 17:20:57

US3302383

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	26 Aug 2020 17:21:01

**US3302383**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User entered '1'	System	26 Aug 2020 17:21:01



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:06:22', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b57b13cf-c57d-49ed-899f-cefd8f520535' User entered 'Yes (Y)'	System	26 Aug 2020 16:06:44
	System	26 Aug 2020 16:06:44

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:06:29', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b57b13cf-c57d-49ed-899f-cefd8f520535' User entered '96.8'	System	26 Aug 2020 16:06:44
	System	26 Aug 2020 16:06:44

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:06:34', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b57b13cf-c57d-49ed-899f-cefd8f520535'	System	26 Aug 2020 16:06:44
User entered 'No (N)'	System	26 Aug 2020 16:06:44

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:06:40', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b57b13cf-c57d-49ed-899f-cefd8f520535'	System	26 Aug 2020 16:06:44
User entered '26 Aug 2020 12:06'	System	26 Aug 2020 16:06:44

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 12:06'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 14:36'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:56:44', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8dc26d03-aaab-4439-a625-326b033164b8' User entered 'Yes (Y)'	System	27 Aug 2020 10:57:06
	System	27 Aug 2020 10:57:06

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:56:53', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8dc26d03-aaab-4439-a625-326b033164b8' User entered '97.8'	System	27 Aug 2020 10:57:06
	System	27 Aug 2020 10:57:06

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:56:58', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8dc26d03-aaab-4439-a625-326b033164b8'	System	27 Aug 2020 10:57:06
User entered 'No (N)'	System	27 Aug 2020 10:57:06

**US3302383**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:04', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8dc26d03-aaab-4439-a625-326b033164b8' User entered '27 Aug 2020 06:57'	System	27 Aug 2020 10:57:06
	System	27 Aug 2020 10:57:06

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 15:31'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 2'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:22', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '31a2add3-cab4-4f0f-aace-2f0a2356a15c' User entered 'Yes (Y)'	System	27 Aug 2020 16:00:41
	System	27 Aug 2020 16:00:41



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '31a2add3-cab4-4f0f-aace-2f0a2356a15c' User entered '97.5'	System	27 Aug 2020 16:00:41
	System	27 Aug 2020 16:00:41

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '31a2add3-cab4-4f0f-aace-2f0a2356a15c'	System	27 Aug 2020 16:00:41
User entered 'No (N)'	System	27 Aug 2020 16:00:41

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:39', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '31a2add3-cab4-4f0f-aeee-2f0a2356a15c'	System	27 Aug 2020 16:00:41
User entered '27 Aug 2020 12:00'	System	27 Aug 2020 16:00:41

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 3'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:03:43', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cbe862f2-3429-4bf0-ac6c-8e6640e47a72'	System	28 Aug 2020 16:05:06
User entered 'Yes (Y)'	System	28 Aug 2020 16:05:06

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:03:51', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cbe862f2-3429-4bf0-ac6c-8e6640e47a72' User entered '97.8'	System	28 Aug 2020 16:05:06
	System	28 Aug 2020 16:05:06



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:03:55', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cbe862f2-3429-4bf0-ac6c-8e6640e47a72'	System	28 Aug 2020 16:05:06
User entered 'No (N)'	System	28 Aug 2020 16:05:06

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:03:59', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cbe862f2-3429-4bf0-ac6c-8e6640e47a72'	System	28 Aug 2020 16:05:06
User entered '28 Aug 2020 12:03'	System	28 Aug 2020 16:05:06

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 4'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:06:49', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '3172c598-89e3-4d9e-9196-28e40c5d0fae' User entered 'Yes (Y)'	System	29 Aug 2020 21:07:14
	System	29 Aug 2020 21:07:14

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:06:56', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '3172c598-89e3-4d9e-9196-28e40c5d0fae' User entered '97.6'	System	29 Aug 2020 21:07:14
	System	29 Aug 2020 21:07:14

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:04', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '3172c598-89e3-4d9e-9196-28e40c5d0fae'	System	29 Aug 2020 21:07:14
User entered 'No (N)'	System	29 Aug 2020 21:07:14



**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:13', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '3172c598-89e3-4d9e-9196-28e40c5d0fae' User entered '29 Aug 2020 17:07'	System	29 Aug 2020 21:07:14
	System	29 Aug 2020 21:07:14

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 5'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:26:58', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '2f544b53-abdd-4549-8cf2-fdf5e6154514'	System	30 Aug 2020 21:27:16
User entered 'Yes (Y)'	System	30 Aug 2020 21:27:16

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:05', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '2f544b53-abdd-4549-8cf2-fdf5e6154514'	System	30 Aug 2020 21:27:16
User entered '96.8'	System	30 Aug 2020 21:27:16

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:09', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '2f544b53-abdd-4549-8cf2-fdf5e6154514'	System	30 Aug 2020 21:27:16
User entered 'No (N)'	System	30 Aug 2020 21:27:16

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:13', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '2f544b53-abdd-4549-8cf2-fdf5e6154514'	System	30 Aug 2020 21:27:16
User entered '30 Aug 2020 17:27'	System	30 Aug 2020 21:27:16



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 6'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '91a83ca1-628f-4bf0-bf97-c41fa04a2490' User entered 'Yes (Y)'	System	01 Sep 2020 13:53:51
	System	01 Sep 2020 13:53:51

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:41', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '91a83ca1-628f-4bf0-bf97-c41fa04a2490' User entered '96.3'	System	01 Sep 2020 13:53:51
	System	01 Sep 2020 13:53:51

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:43', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '91a83ca1-628f-4bf0-bf97-c41fa04a2490' User entered 'No (N)'	System	01 Sep 2020 13:53:51
	System	01 Sep 2020 13:53:51

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:46', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '91a83ca1-628f-4bf0-bf97-c41fa04a2490' User entered '01 Sep 2020 09:53'	System	01 Sep 2020 13:53:51
	System	01 Sep 2020 13:53:51

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 7'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:13', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '040753e4-63e8-496c-8fcf-d3ba19e124bd' User entered 'Yes (Y)'	System	01 Sep 2020 18:11:26
	System	01 Sep 2020 18:11:26

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:19', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '040753e4-63e8-496c-8fcf-d3ba19e124bd' User entered '97.1'	System	01 Sep 2020 18:11:26
	System	01 Sep 2020 18:11:26

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:21', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '040753e4-63e8-496c-8fcf-d3ba19e124bd' User entered 'No (N)'	System	01 Sep 2020 18:11:26
	System	01 Sep 2020 18:11:26

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '040753e4-63e8-496c-8fcf-d3ba19e124bd' User entered '01 Sep 2020 14:11'	System	01 Sep 2020 18:11:26
	System	01 Sep 2020 18:11:26

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:03', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '11592af1-6c0b-49ee-b7e4-96039f38924c' User entered 'None (1)'	System	26 Aug 2020 16:07:22
	System	26 Aug 2020 16:07:22

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:07', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '11592af1-6c0b-49ee-b7e4-96039f38924c' User entered 'No (N)'	System	26 Aug 2020 16:07:22
	System	26 Aug 2020 16:07:22

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:10', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '11592af1-6c0b-49ee-b7e4-96039f38924c' User entered 'No (N)'	System	26 Aug 2020 16:07:22
	System	26 Aug 2020 16:07:22

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:14', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '11592af1-6c0b-49ee-b7e4-96039f38924c' User entered 'None (1)'	System	26 Aug 2020 16:07:22
	System	26 Aug 2020 16:07:22

**US3302383**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:20', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '11592af1-6c0b-49ee-b7e4-96039f38924c' User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:22
	System	26 Aug 2020 16:07:22

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 12:06'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 14:36'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:15', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '15ccfd3c-9a1f-4649-8073-6d5255a7141c' User entered 'None (1)'	System	27 Aug 2020 10:57:49
	System	27 Aug 2020 10:57:49

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:30', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '15ccfd3c-9a1f-4649-8073-6d5255a7141c' User entered 'No (N)'	System	27 Aug 2020 10:57:49
	System	27 Aug 2020 10:57:49

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:39', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '15ccfd3c-9a1f-4649-8073-6d5255a7141c' User entered 'No (N)'	System	27 Aug 2020 10:57:49
	System	27 Aug 2020 10:57:49

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:43', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '15ccfd3c-9a1f-4649-8073-6d5255a7141c' User entered 'None (1)'	System	27 Aug 2020 10:57:49
	System	27 Aug 2020 10:57:49

**US3302383**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:47', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '15ccfd3c-9a1f-4649-8073-6d5255a7141c' User entered '27 Aug 2020 06:57'	System	27 Aug 2020 10:57:49
	System	27 Aug 2020 10:57:49

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 15:31'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 2'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:44', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'efc7a218-447c-417f-af2f-480602fdd2e7'	System	27 Aug 2020 16:01:08
User entered 'None (1)'	System	27 Aug 2020 16:01:08

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:49', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'efc7a218-447c-417f-af2f-480602fdd2e7'	System	27 Aug 2020 16:01:08
User entered 'No (N)'	System	27 Aug 2020 16:01:08

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:52', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'efc7a218-447c-417f-af2f-480602fdd2e7'	System	27 Aug 2020 16:01:08
User entered 'No (N)'	System	27 Aug 2020 16:01:08

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:54', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'efc7a218-447c-417f-af2f-480602fdd2e7'	System	27 Aug 2020 16:01:08
User entered 'None (1)'	System	27 Aug 2020 16:01:08

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:00:58', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'efc7a218-447c-417f-af2f-480602fdd2e7' User entered '27 Aug 2020 12:00'	System	27 Aug 2020 16:01:08
	System	27 Aug 2020 16:01:08

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 3'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:03', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '37f9af3f-78c4-441d-b9bd-aa870452778d' User entered 'None (1)'	System	28 Aug 2020 16:05:21
	System	28 Aug 2020 16:05:21

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:07', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '37f9af3f-78c4-441d-b9bd-aa870452778d' User entered 'No (N)'	System	28 Aug 2020 16:05:21
	System	28 Aug 2020 16:05:21

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:10', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '37f9af3f-78c4-441d-b9bd-aa870452778d' User entered 'No (N)'	System	28 Aug 2020 16:05:21
	System	28 Aug 2020 16:05:21

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:13', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '37f9af3f-78c4-441d-b9bd-aa870452778d' User entered 'None (1)'	System	28 Aug 2020 16:05:21
	System	28 Aug 2020 16:05:21

**US3302383**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:16', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '37f9af3f-78c4-441d-b9bd-aa870452778d' User entered '28 Aug 2020 12:04'	System	28 Aug 2020 16:05:21
	System	28 Aug 2020 16:05:21

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 4'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '89101127-baec-4cab-a325-3f1b69642a6c' User entered 'None (1)'	System	29 Aug 2020 21:07:44
	System	29 Aug 2020 21:07:44

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:27', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '89101127-baec-4cab-a325-3f1b69642a6c' User entered 'No (N)'	System	29 Aug 2020 21:07:44
	System	29 Aug 2020 21:07:44

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:34', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '89101127-baec-4cab-a325-3f1b69642a6c' User entered 'No (N)'	System	29 Aug 2020 21:07:44
	System	29 Aug 2020 21:07:44

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:39', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '89101127-baec-4cab-a325-3f1b69642a6c' User entered 'None (1)'	System	29 Aug 2020 21:07:44
	System	29 Aug 2020 21:07:44

**US3302383**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:42', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '89101127-baec-4cab-a325-3f1b69642a6c' User entered '29 Aug 2020 17:07'	System	29 Aug 2020 21:07:44
	System	29 Aug 2020 21:07:44

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

**US3302383**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 5'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:16', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b4b9de3c-df98-472e-ada6-5c3647e7a5dd'	System	30 Aug 2020 21:27:30
User entered 'None (1)'	System	30 Aug 2020 21:27:30

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:22', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b4b9de3c-df98-472e-ada6-5c3647e7a5dd' User entered 'No (N)'	System	30 Aug 2020 21:27:30
	System	30 Aug 2020 21:27:30

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b4b9de3c-df98-472e-ada6-5c3647e7a5dd' User entered 'No (N)'	System	30 Aug 2020 21:27:30
	System	30 Aug 2020 21:27:30

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:26', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b4b9de3c-df98-472e-ada6-5c3647e7a5dd' User entered 'None (1)'	System	30 Aug 2020 21:27:30
	System	30 Aug 2020 21:27:30

**US3302383**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:28', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'b4b9de3c-df98-472e-ada6-5c3647e7a5dd' User entered '30 Aug 2020 17:27'	System	30 Aug 2020 21:27:30
	System	30 Aug 2020 21:27:30

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 6'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:50', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '30d0e6ea-f925-4e02-ab26-c6e9da58bc9b' User entered 'None (1)'	System	01 Sep 2020 13:54:03
	System	01 Sep 2020 13:54:03

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:53', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '30d0e6ea-f925-4e02-ab26-c6e9da58bc9b' User entered 'No (N)'	System	01 Sep 2020 13:54:03
	System	01 Sep 2020 13:54:03

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:54', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '30d0e6ea-f925-4e02-ab26-c6e9da58bc9b' User entered 'No (N)'	System	01 Sep 2020 13:54:03
	System	01 Sep 2020 13:54:03

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:56', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '30d0e6ea-f925-4e02-ab26-c6e9da58bc9b' User entered 'None (1)'	System	01 Sep 2020 13:54:03
	System	01 Sep 2020 13:54:03

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:53:58', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '30d0e6ea-f925-4e02-ab26-c6e9da58bc9b' User entered '01 Sep 2020 09:53'	System	01 Sep 2020 13:54:03
	System	01 Sep 2020 13:54:03

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 7'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:28', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8e53153c-2227-4c41-b761-612c82102fe1' User entered 'None (1)'	System	01 Sep 2020 18:11:41
	System	01 Sep 2020 18:11:41

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:30', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8e53153c-2227-4c41-b761-612c82102fe1' User entered 'No (N)'	System	01 Sep 2020 18:11:41
	System	01 Sep 2020 18:11:41

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:33', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8e53153c-2227-4c41-b761-612c82102fe1' User entered 'No (N)'	System	01 Sep 2020 18:11:41
	System	01 Sep 2020 18:11:41

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8e53153c-2227-4c41-b761-612c82102fe1' User entered 'None (1)'	System	01 Sep 2020 18:11:41
	System	01 Sep 2020 18:11:41

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:38', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8e53153c-2227-4c41-b761-612c82102fe1' User entered '01 Sep 2020 14:11'	System	01 Sep 2020 18:11:41
	System	01 Sep 2020 18:11:41

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:27', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:30', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:33', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:36', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered 'None (0)'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:41', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975'	System	26 Aug 2020 16:07:52
User entered 'No (N)'	System	26 Aug 2020 16:07:52



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-26T12:07:47', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'dcb8d4b4-c9d7-420c-9258-3834cc8e7975' User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:52
	System	26 Aug 2020 16:07:52

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 12:06'	System	26 Aug 2020 15:55:24

**US3302383**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 14:36'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:53', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:55', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:57', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:57:59', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:58:01', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:58:03', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193' User entered 'None (0)'	System	27 Aug 2020 10:58:22
	System	27 Aug 2020 10:58:22

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:58:08', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193'	System	27 Aug 2020 10:58:22
User entered 'No (N)'	System	27 Aug 2020 10:58:22

**US3302383**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T06:58:18', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'a99919fc-660d-41b1-bdec-28a1dcc8d193'	System	27 Aug 2020 10:58:22
User entered '27 Aug 2020 06:58'	System	27 Aug 2020 10:58:22

**US3302383**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '26 Aug 2020 15:31'	System	26 Aug 2020 15:55:24

**US3302383**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:00:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 2'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:05', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:09', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:11', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:13', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:15', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:16', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'None (0)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:22', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered 'No (N)'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-27T12:01:26', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1a04e1a2-fb71-4ac8-ba66-67458fdf76eb' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:40
	System	27 Aug 2020 16:01:40

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:55:24



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 3'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:19', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:21', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:23', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:26', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:28', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'None (0)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:37', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered 'No (N)'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-28T12:04:41', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '470d3dc4-3219-4a56-9d7c-18abda69398c' User entered '28 Aug 2020 12:04'	System	28 Aug 2020 16:05:42
	System	28 Aug 2020 16:05:42

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 4'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:45', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:47', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:49', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:50', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:52', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:07:53', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered 'None (0)'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:08:02', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610'	System	29 Aug 2020 21:08:14
User entered 'No (N)'	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-29T17:08:10', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'da319458-15aa-4b7d-824d-98161ebbf610' User entered '29 Aug 2020 17:08'	System	29 Aug 2020 21:08:14
	System	29 Aug 2020 21:08:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 5'	System	26 Aug 2020 15:55:24



**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:32', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:34', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:36', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:37', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:39', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:40', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'None (0)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:42', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered 'No (N)'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-08-30T17:27:45', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f57c9e5e-0d0a-470f-8649-d0b4d4989038' User entered '30 Aug 2020 17:27'	System	30 Aug 2020 21:27:47
	System	30 Aug 2020 21:27:47



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:55:24

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 6'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:01', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:03', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:04', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:05', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:07', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:08', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'None (0)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:09', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4' User entered 'No (N)'	System	01 Sep 2020 13:54:14
	System	01 Sep 2020 13:54:14

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T09:54:12', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'cd33e4ac-241d-49bf-a6bc-63aca787b1b4'	System	01 Sep 2020 13:54:14
User entered '01 Sep 2020 09:54'	System	01 Sep 2020 13:54:14

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 7'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:41', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:42', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57



US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:44', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:45', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:46', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:48', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'None (0)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:52', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered 'No (N)'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

**US3302383**

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

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

**Generated On: 09 Jun 2021 17:00:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-09-01T14:11:55', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '0fbde840-4e32-4fba-be82-abaf456f55ad' User entered '01 Sep 2020 14:11'	System	01 Sep 2020 18:11:57
	System	01 Sep 2020 18:11:57

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:55:24

US3302383

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	02 Sep 2020 14:55:50

US3302383

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	10 Nov 2020 22:19:27
User entered '2 Sep 2020'	(b) (4)	
	Wendy Taylor (b) (4)	02 Sep 2020 14:55:50

US3302383

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	02 Sep 2020 14:55:50

US3302383

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:43:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	02 Sep 2020 14:55:50

US3302383

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Sep 2020 14:55:56

US3302383

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User entered '1'	System	02 Sep 2020 14:55:56

US3302383

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	02 Sep 2020 15:00:12

US3302383

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 17:26:23
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	10 Sep 2020 17:26:23
User entered '10 Sep 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	10 Sep 2020 17:26:23
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Sep 2020 15:00:12
User entered '2 Sep 2020'	Wendy Taylor (b) (4)	02 Sep 2020 15:00:12



US3302383

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	02 Sep 2020 15:00:12

US3302383

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) Wendy Taylor (b) (4)	02 Sep 2020 15:00:12

US3302383

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	10 Sep 2020 17:26:27

US3302383

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User entered 'I'	System	10 Sep 2020 17:26:27

US3302383

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 17:53:25

US3302383

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '17 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 17:53:25

US3302383

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 17:53:25

US3302383

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 17:53:25



US3302383

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	17 Sep 2020 17:53:33

**US3302383**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:42:08
User entered 'I'	System	17 Sep 2020 17:53:33

US3302383

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	brittany cooksey (b) (4)	17 Dec 2020 15:03:02

US3302383

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	17 Dec 2020 15:03:02

US3302383

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[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 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	17 Dec 2020 15:03:02

US3302383

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'VISIT2'	System	17 Dec 2020 15:03:02

US3302383

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	Wendy Taylor (b) (4)	16 Oct 2020 16:43:17

US3302383

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:43:17



US3302383

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:43:17

US3302383

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'subject completing convulsant phase' reason for change: Data Entry Error	(b) (4) Wendy Taylor (b) (4)	16 Oct 2020 16:43:52
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:43:17

US3302383

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	16 Oct 2020 16:43:23

US3302383

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	16 Oct 2020 16:43:23

US3302383

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	Wendy Taylor (b) (4)	16 Oct 2020 16:44:17

US3302383

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:44:17

US3302383

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:44:17

US3302383

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'pt is in convulsant phase' reason for change: Data Entry Error	Wendy Taylor (b) (4)	16 Oct 2020 16:45:05
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:44:17



US3302383

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	16 Oct 2020 16:44:02

**US3302383**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	16 Oct 2020 16:44:02

US3302383

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	16 Oct 2020 16:45:17

US3302383

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '16 Oct 2020'	Wendy Taylor (b) (4)	16 Oct 2020 16:45:17

US3302383

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	16 Oct 2020 16:45:17

US3302383

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	Wendy Taylor (b) (4)	16 Oct 2020 16:45:17

US3302383

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	16 Oct 2020 16:45:22

US3302383

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	16 Oct 2020 16:45:22



US3302383

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	brittany cooksey (b) (4)	17 Dec 2020 15:03:14

US3302383

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	17 Dec 2020 15:03:14

US3302383

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[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 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	17 Dec 2020 15:03:14

**US3302383**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'VISIT3'	System	17 Dec 2020 15:03:14

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 64'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-10-28T10:25:44', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1518c341-dd56-4a74-b018-18e219ce50dc' User entered 'No (N)'	System	28 Oct 2020 14:26:03
	System	28 Oct 2020 14:26:03

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-10-28T10:25:49', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1518c341-dd56-4a74-b018-18e219ce50dc'	System	28 Oct 2020 14:26:03
User entered 'No (N)'	System	28 Oct 2020 14:26:03

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-10-28T10:26:01', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1518c341-dd56-4a74-b018-18e219ce50dc' User entered '28 Oct 2020 10:26:01'	System	28 Oct 2020 14:26:03
	System	28 Oct 2020 14:26:03



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 71'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-03T12:04:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '87ab75a8-c1e2-4149-9ffb-570f37626ac3'	System	03 Nov 2020 17:04:59
User entered 'No (N)'	System	03 Nov 2020 17:04:59

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-03T12:04:28', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '87ab75a8-c1e2-4149-9ffb-570f37626ac3'	System	03 Nov 2020 17:04:59
User entered 'No (N)'	System	03 Nov 2020 17:04:59

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-03T12:04:33', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '87ab75a8-c1e2-4149-9ffb-570f37626ac3' User entered '03 Nov 2020 12:04:33'	System	03 Nov 2020 17:04:59
	System	03 Nov 2020 17:04:59

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 15:55:24

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 15:55:24



US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered 'Day 78'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-09T17:06:52', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'e50a0eaf-6014-4d0d-98d8-fcccc4e35811'	System	09 Nov 2020 22:07:06
User entered 'No (N)'	System	09 Nov 2020 22:07:06

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-09T17:06:56', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'e50a0eaf-6014-4d0d-98d8-fcccc4e35811'	System	09 Nov 2020 22:07:06
User entered 'No (N)'	System	09 Nov 2020 22:07:06

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-09T17:07:02', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'e50a0eaf-6014-4d0d-98d8-fccccc4e35811' User entered '09 Nov 2020 17:07:02'	System	09 Nov 2020 22:07:06
	System	09 Nov 2020 22:07:06

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 15:55:24

US3302383

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:54:24
Data entry locked.	System	26 Aug 2020 15:55:24
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 15:55:24

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-27T06:30:09', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '460a9a2a-28bc-4389-903f-59212ab731f2'	System	27 Nov 2020 11:30:26
User entered 'No (N)'	System	27 Nov 2020 11:30:26



US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-27T06:30:15', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '460a9a2a-28bc-4389-903f-59212ab731f2'	System	27 Nov 2020 11:30:26
User entered 'No (N)'	System	27 Nov 2020 11:30:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-11-27T06:30:21', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '460a9a2a-28bc-4389-903f-59212ab731f2' User entered '27 Nov 2020 06:30:21'	System	27 Nov 2020 11:30:26
	System	27 Nov 2020 11:30:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-04T08:38:43', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8429bc45-a071-4c06-a892-0cecf5f7aac0' User entered 'No (N)'	System	04 Dec 2020 13:38:59
	System	04 Dec 2020 13:38:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-04T08:38:52', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8429bc45-a071-4c06-a892-0cecf5f7aac0' User entered 'No (N)'	System	04 Dec 2020 13:38:59
	System	04 Dec 2020 13:38:59

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-04T08:38:57', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '8429bc45-a071-4c06-a892-0cecf5f7aac0' User entered '04 Dec 2020 08:38:57'	System	04 Dec 2020 13:38:59
	System	04 Dec 2020 13:38:59



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-12T08:03:55', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '27106cff-11fb-4c33-8925-ced882edd049'	System	12 Dec 2020 13:04:05
User entered 'No (N)'	System	12 Dec 2020 13:04:05

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-12T08:03:59', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '27106cff-11fb-4c33-8925-ced882edd049'	System	12 Dec 2020 13:04:05
User entered 'No (N)'	System	12 Dec 2020 13:04:05

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-12T08:04:03', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '27106cff-11fb-4c33-8925-ced882edd049' User entered '12 Dec 2020 08:04:03'	System	12 Dec 2020 13:04:05
	System	12 Dec 2020 13:04:05

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:08:26



US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-18T05:23:54', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '7cbb9ae3-ce8e-4ad3-91ec-bb8b0ed88fce'	System	18 Dec 2020 10:24:32
User entered 'No (N)'	System	18 Dec 2020 10:24:32

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-18T05:24:04', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '7cbb9ae3-ce8e-4ad3-91ec-bb8b0ed88fce'	System	18 Dec 2020 10:24:32
User entered 'No (N)'	System	18 Dec 2020 10:24:32

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-18T05:24:30', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '7cbb9ae3-ce8e-4ad3-91ec-bb8b0ed88fce' User entered '18 Dec 2020 05:24:30'	System	18 Dec 2020 10:24:32
	System	18 Dec 2020 10:24:32

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-25T06:52:11', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '4abb3538-b255-442e-98c1-237134fdf81d' User entered 'No (N)'	System	25 Dec 2020 12:12:50
	System	25 Dec 2020 12:12:50



US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-25T06:52:19', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '4abb3538-b255-442e-98c1-237134fdf81d' User entered 'No (N)'	System	25 Dec 2020 12:12:50
	System	25 Dec 2020 12:12:50

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2020-12-25T06:52:23', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '4abb3538-b255-442e-98c1-237134fdf81d' User entered '25 Dec 2020 06:52:23'	System	25 Dec 2020 12:12:50
	System	25 Dec 2020 12:12:50

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-01T00:01:26', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '70938d4b-937a-421a-a53d-9c3d7f065e7b' User entered 'No (N)'	System	01 Jan 2021 05:02:40
	System	01 Jan 2021 05:02:40

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-01T00:01:34', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '70938d4b-937a-421a-a53d-9c3d7f065e7b' User entered 'No (N)'	System	01 Jan 2021 05:02:40
	System	01 Jan 2021 05:02:40

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-01T00:02:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '70938d4b-937a-421a-a53d-9c3d7f065e7b' User entered '01 Jan 2021 00:02:35'	System	01 Jan 2021 05:02:40
	System	01 Jan 2021 05:02:40



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-09T20:07:24', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f04817ab-f159-4f97-8df9-de7786391cb9' User entered 'No (N)'	System	10 Jan 2021 01:07:45
	System	10 Jan 2021 01:07:45

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-09T20:07:33', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f04817ab-f159-4f97-8df9-de7786391cb9'	System	10 Jan 2021 01:07:45
User entered 'No (N)'	System	10 Jan 2021 01:07:45

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-09T20:07:42', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: 'f04817ab-f159-4f97-8df9-de7786391cb9' User entered '09 Jan 2021 20:07:42'	System	10 Jan 2021 01:07:45
	System	10 Jan 2021 01:07:45

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:08:26



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-16T19:24:35', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1b31c9eb-c33b-4402-8d74-9842498b5bf9' User entered 'No (N)'	System	17 Jan 2021 00:25:00
	System	17 Jan 2021 00:25:00

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-16T19:24:51', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1b31c9eb-c33b-4402-8d74-9842498b5bf9'	System	17 Jan 2021 00:25:00
User entered 'No (N)'	System	17 Jan 2021 00:25:00

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-16T19:24:57', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '1b31c9eb-c33b-4402-8d74-9842498b5bf9' User entered '16 Jan 2021 19:24:57'	System	17 Jan 2021 00:25:00
	System	17 Jan 2021 00:25:00

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-22T07:17:47', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '35eada16-ddec-46ca-803f-e3c6ad92efce' User entered 'No (N)'	System	22 Jan 2021 12:18:03
	System	22 Jan 2021 12:18:03



US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-22T07:17:54', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '35eada16-ddec-46ca-803f-e3c6ad92efce'	System	22 Jan 2021 12:18:03
User entered 'No (N)'	System	22 Jan 2021 12:18:03

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-22T07:18:01', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '35eada16-ddec-46ca-803f-e3c6ad92efce' User entered '22 Jan 2021 07:18:01'	System	22 Jan 2021 12:18:03
	System	22 Jan 2021 12:18:03

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-29T10:39:44', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '112b87db-33f0-4f0b-b0b9-b2f0894b843d' User entered 'No (N)'	System	29 Jan 2021 15:39:59
	System	29 Jan 2021 15:39:59

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-29T10:39:50', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '112b87db-33f0-4f0b-b0b9-b2f0894b843d' User entered 'No (N)'	System	29 Jan 2021 15:39:59
	System	29 Jan 2021 15:39:59

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-01-29T10:39:56', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '112b87db-33f0-4f0b-b0b9-b2f0894b843d' User entered '29 Jan 2021 10:39:56'	System	29 Jan 2021 15:39:59
	System	29 Jan 2021 15:39:59



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:08:26

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:50:56', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered 'Yes (Y)'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you been exposed to someone with 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)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:00', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered 'Yes (Y)'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:11', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf'	System	05 Feb 2021 11:51:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:16', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered 'Yes (Y)'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '1'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:31', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '0'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58



**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:34', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf'	System	05 Feb 2021 11:51:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 11:51:58

US3302383

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:55

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:40', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered 'Yes (Y)'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:43', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf'	System	05 Feb 2021 11:51:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (44C90531-91F1-43EA-B294-DF4EA7310268)', Time: '2021-02-05T06:51:49', User OID: 'PatientReportedOutcome (US3302383)', ODM File OID: '69f7d3d8-77b9-4013-9e48-53d1231906cf' User entered '05 Feb 2021 06:51:49'	System	05 Feb 2021 11:51:58
	System	05 Feb 2021 11:51:58

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:08:26

**US3302383**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:08:26
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:08:26

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:26
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (22Sep 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:23:13
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (22Sep 2020). Please review and reconcile.' answered with 'entered is correct, please confirm what else is needed' (Site from DM).	brittany cooksey (b) (4)	12 Jan 2021 19:36:33
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (22Sep 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:19:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:47:54
User entered '22 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:52:59

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:26
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:47:54
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 19:46:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 19:46:29
User entered '17:13' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 19:46:29
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:52:59
User entered empty.	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:52:59



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:26
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '22 Sep 2020 17:13'	System	05 Oct 2020 19:46:29
User entered empty.	System	30 Sep 2020 16:52:59

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:26
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:47:54
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	brittany cooksey (b) (4)	30 Sep 2020 16:52:59

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:26
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:47:54
User entered 'Yes (Y)'	brittany cooksey (b) (4)	30 Sep 2020 16:52:59

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 1 (Day 1)'	(b) (4) brittany cooksey (b) (4)	30 Sep 2020 16:55:02
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Please confirm that initial start date of symptoms and Contact date are the same (22SEP2020) or update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:21:36
Query 'Per CDM: Please confirm that initial start date of symptoms and Contact date are the same (22SEP2020) or update accordingly' answered with 'confirmed as same date' (Site from DM).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 21:38:55
User opened query 'Per CDM: Please confirm that initial start date of symptoms and Contact date are the same (22SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:04:57
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '22 Sep 2020'	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:45:05
User closed query 'Per CDM: It appears data is missing for day 1,2,8 and 9 . Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:00:36
Query 'Per CDM: It appears data is missing for day 1,2,8 and 9 . Please review and update accordingly.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	14 Jan 2021 00:33:04
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:32:55
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	14 Jan 2021 00:32:55
User opened query 'Per CDM: It appears data is missing for day 1,2,8 and 9 . Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:23:16
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:32:55
User entered empty.	System	30 Sep 2020 16:55:02



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '98.0' F	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:51:27
User closed query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:51:24
Query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" answered with 'entry error' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 16:28:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:28:11
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User opened query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:34:11
User closed query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:34:11
Query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" answered with 'late note entered in source' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:09:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
User opened query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea, but source does not mention "Chills" (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:55:09
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'Mild (Mild)'	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:10
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:11
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:14
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:34:51
User closed query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:34:48
Query 'Please review source and revise if needed. Onbrittany cooksey Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' answered with 'updated' (Site from CRA).	(b) (4)	03 Nov 2020 14:10:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:10:13
User opened query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:51:53
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 15:50:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:21
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:23
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:25
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:39
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:43
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:45
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:46
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:35:02
User closed query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:34:59
Query 'Please review source and revise if needed. Onbrittany cooksey Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' answered with 'updated' (Site from CRA).	(b) (4)	03 Nov 2020 14:10:28
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:10:13
User opened query 'Please review source and revise if needed. On Progress notes in Source it states that the subject had symptoms of Fatigue, Weakness, Fever, and Nausea.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:53:42
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 15:53:36
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:51
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:53
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:48:55
DataPoint Un-verified.	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	12 Jan 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:55:02

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 2 (Day 2)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '23 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '98'	brittany cooksey (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '100.4' F	brittany cooksey (b) (4)	30 Sep 2020 16:56:22



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:51:54
User closed query '? Please review source and revise if needed. Source does not state that subject had chills' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:51:52
Query '? Please review source and revise if needed. Source does not state that subject had chills' answered with 'entry error' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 16:28:45
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 16:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User opened query '? Please review source and revise if needed. Source does not state that subject had chills' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:35:47
User closed query 'Please review source and revise if needed. Source does not state that subject had chills.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:35:47
Query 'Please review source and revise if needed. Source does not state that subject had chills.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:10:48
User opened query 'Please review source and revise if needed. Source does not state that subject had chills.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:59:37
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 15:59:06
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you! ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:47:18
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you! ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:11:56
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:11:43
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:11:43
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you! ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:45:54
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:20:58
User closed query 'Please review progress notes in CRIO for 22Sep2020 and revise if needed. Progress notes state that the subject had symptoms of fatigue.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:20:41
Query 'Please review progress notes in CRIO for 22Sep2020 and revise if needed. Progress notes state that the subject had symptoms of fatigue.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	06 Apr 2021 14:48:56
Signature has been broken.	Brittany Belcher (b) (4)	06 Apr 2021 14:28:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	06 Apr 2021 14:28:06
User opened query 'Please review progress notes in CRIO for 22Sep2020 and revise if needed. Progress notes state that the subject had symptoms of fatigue.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 13:09:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:07:11
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:48
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:09:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 16:56:22
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 3 (Day 3)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '24 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'I'	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:50:49
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:34:17
User entered empty.	System	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:50:51
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 4 (Day 4)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '25 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:57:35



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'I'	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:51:07
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:34:17
User entered empty.	System	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:51:09
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:57:35

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 5 (Day 5)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '26 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'I'	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:51:35
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:34:17
User entered empty.	System	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:51:37
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:11

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 6 (Day 6)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '27 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'I'	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:04
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:34:17
User entered empty.	System	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:06
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:58:39



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 7 (Day 7)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '28 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'I'	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:53
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	14 Jan 2021 00:34:17
User entered empty.	System	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:52:55
DataPoint Un-verified.	brittany cooksey (b) (4)	14 Jan 2021 00:34:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 00:34:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 16:59:49

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 8 (Day 8)'	(b) (4) brittany cooksey (b) (4) (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '29 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 17:01:41



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '98'	brittany cooksey (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '98.2' F	brittany cooksey (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:49
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:48:00
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated per source' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:14:01
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:13:51
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:13:51
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:11:38
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 17:01:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:53
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:56
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:11:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:06
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:12:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:01:41
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please enter Day 10 Illness Call.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:36:22
Query 'Please enter Day 10 Illness Call.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 17:13:23
User opened query 'Please enter Day 10 Illness Call.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:08:52
User entered 'Day 9 (Day 9)'	brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '30 Sep 2020'	brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '99'	brittany cooksey (b) (4)	30 Sep 2020 17:02:03



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Oct 2020 19:46:43
User entered '97.2' F reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Oct 2020 19:46:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Sep 2020 17:02:03
User entered '97.2' (non-conformant).	brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:48:05
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:18:47
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:18:35
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:18:35
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:11:45
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4) brittany cooksey (b) (4)	01 Feb 2021 20:18:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4) brittany cooksey (b) (4)	30 Sep 2020 17:02:03

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:13:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:18:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 17:02:03
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 10 (Day 10)'	(b) (4) brittany cooksey (b) (4) (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:06
User entered '01 Oct 2020'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:09
User entered '0'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:12
User entered '99'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:15
User entered '97.3' F	brittany cooksey (b) (4)	03 Nov 2020 17:13:12



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:17
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:20
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:23
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:26
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:29
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:31
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:34
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:37
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:40
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:43
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:46
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:48
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:51
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:54
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:57
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:37:59
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:13:12



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 11 (Day 11)'	(b) (4) brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '02 Oct 2020'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please review source and revise if needed. Source states that pulse oxygen was 97%.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:38:14
Query 'Please review source and revise if needed. Source states that pulse oxygen was 97%.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:40:57
User entered '97' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:40:50
User opened query 'Please review source and revise if needed. Source states that pulse oxygen was 97%.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:09:39
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:09:09
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '99'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '97.3' F	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:48:15
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:21:35
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:21:11
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:21:11
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:12:01
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 19:49:24



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 12 (Day 12)'	(b) (4) brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '03 Oct 2020'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:38:27
Query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 12 in source.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:41:59
User entered '99' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:41:18
User opened query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:11:10
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:10:11
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '97'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please review source and revise if needed. Temperature is listed as 97.9 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:38:33
Query 'Please review source and revise if needed. Temperature is listed as 97.9 for Day 12 in source.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:41:26
User entered '97.9' F reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:41:18
User opened query 'Please review source and revise if needed. Temperature is listed as 97.9 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '97.3' F	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:48:20
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:23:13
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:22:58
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:22:58
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:12:07
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:22:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 13 (Day 13)'	(b) (4) brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '04 Oct 2020'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:38:55
User closed query 'Please review source and revise if needed. O2 saturation is listed as 98% for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:47
Query 'Please review source and revise if needed. O2 saturation is listed as 98% for Day 12 in source.' answered with 'updated' (Site from CRA).	O2brittany cooksey (b) (4)	03 Nov 2020 14:42:25
User entered '98' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 14:42:14
User opened query 'Please review source and revise if needed. O2 saturation is listed as 98% for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:12:16
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:58
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '99'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:38:53
User closed query 'Please review source and revise if needed. Temperature is listed as 97.1 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:38:50
Query 'Please review source and revise if needed. Temperature is listed as 97.1 for Day 12 in source.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:42:27
User entered '97.1' F reason for change: Data Entry Error	(b) (4)	03 Nov 2020 14:42:14
User opened query 'Please review source and revise if needed. Temperature is listed as 97.1 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:12:39
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:12:00
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '97.9' F	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:48:27
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:24:23
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:24:13
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:24:13
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:12:15
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:14:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:24:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please add rest of illness visit calls to Symptom log. (Day 15-Day 22)' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:39:32
Query 'Please add rest of illness visit calls to Symptom log. (Day 15-Day 22)' answered with 'day 15 added. no information for other days' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 17:19:11
User opened query 'Please add rest of illness visit calls to Symptom log. (Day 15-Day 22)' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 03:04:43
User entered 'Day 14 (Day 14)'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '05 Oct 2020'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '0'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 14 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:39:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:39:38
Query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 14 in source.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 17:14:21
User entered '99' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 17:14:05
User opened query 'Please review source and revise if needed. O2 saturation is listed as 99% for Day 14 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:13:50
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:13:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '98'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:39:53
User closed query 'Please review source and revise if needed. Temperature is listed as 97.4 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:39:50
Query 'Please review source and revise if needed. Temperature is listed as 97.4 for Day 12 in source.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 17:14:18
User entered '97.4' F reason for change: Data Entry Error	(b) (4)	03 Nov 2020 17:14:05
User opened query 'Please review source and revise if needed. Temperature is listed as 97.4 for Day 12 in source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:14:13
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:13:30
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered '97.1' F	brittany cooksey (b) (4)	05 Oct 2020 19:49:24



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered 'None (None)'	brittany cooksey (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:49:00
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:29:01
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:28:46
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	01 Feb 2021 20:28:46
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:12:22
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4) (b) (4)	05 Oct 2020 19:49:24

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 15:49:30
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:15:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	brittany cooksey (b) (4)	01 Feb 2021 20:28:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:49:30
	(b) (4)	
User entered empty.	brittany cooksey (b) (4)	05 Oct 2020 19:49:24
	(b) (4)	



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Day 15 (Day 15)'	(b) (4) brittany cooksey (b) (4) (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 19OCT2020. Please reconciel or clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:14:38
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 19OCT2020. Please reconciel or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:05:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered '07 Oct 2020'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered '0'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered '99'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '%'	System	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered '97.6' F	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:32
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:28
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:25
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:22
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:20
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:00:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:40:17
User entered 'None (None)'	brittany cooksey (b) (4)	03 Nov 2020 17:18:41

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 05OCT2020 for Day 14 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 10:41:29
Query 'Per GCL Lab Recon: Saliva: Samples dated 05OCT2020 for Day 14 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'log now updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 17:19:59
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 05OCT2020 for Day 14 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:00:58
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 22:08:39
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 'already entered' (Site from System).	Wendy Taylor (b) (4)	08 Oct 2020 12:52:15
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	08 Oct 2020 12:51:46
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[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)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:02
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:51:46

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:00:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:33
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'l'	System	08 Oct 2020 12:51:46



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

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)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:17:17
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 12:53:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 12:53:25
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	08 Oct 2020 12:53:25
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 12:53:16
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16



US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered 'No (N)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:00:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:37
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:51
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:17
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:53:16

US3302383

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:00:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:00:41
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:24:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:08:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 17:37:15

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 3 (Day 3)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10
	(b) (4)	

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:18:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:18:26
User entered '24 Sep 2020'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 5 (Day 5)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10
	(b) (4)	



**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:19:41
User entered 'Yes (Y)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:19:43
User entered '26 Sep 2020'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 7 (Day 7)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10
	(b) (4)	

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:00:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:20:07
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:39:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:39:59
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:12:10
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:20:08
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 9 (Day 9)'	brittany cooksey (b) (4)	03 Nov 2020 14:12:10
	(b) (4)	

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:00:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:20:41
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:39:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:39:59
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:12:10
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:20:43
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10



**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:55**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 14 (Day 14)'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:00:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:21:17
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:39:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:39:59
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:12:10
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:21:19
User entered '05 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, please ship the sample and confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:00:38
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, please ship the sample and confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'confirmed in source that subject lost day 21' (Site from DM).	brittany cooksey (b) (4) (b) (4)	22 Jan 2021 19:37:52
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, please ship the sample and confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:24:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:24:27
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'Day 3 ,5 and 14 are only samples I have showing as received' (Site from DM).	brittany cooksey (b) (4) (b) (4)	11 Jan 2021 21:25:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 03:01:37

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12,19OCT2020 is recorded under Illness Visit Day 21,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:01:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12,19OCT2020 is recorded under Illness Visit Day 21,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'all samples received have been shipped' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 19:28:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12,19OCT2020 is recorded under Illness Visit Day 21,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:44:19
User accepted default value 'Day 21 (Day 21)'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:00:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:18:45
DataPoint Un-verified.	brittany cooksey (b) (4)	22 Jan 2021 19:37:37
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	22 Jan 2021 19:37:37
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:21:34
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:39:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:39:59
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:12:10
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:18:49
DataPoint Un-verified.	brittany cooksey (b) (4)	22 Jan 2021 19:37:37
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	22 Jan 2021 19:37:37
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:21:36
User entered '12 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

**US3302383**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:00:55**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User accepted default value 'Day 28 (Day 28)'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 14:12:10



US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:00:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:53:14
User closed query 'Please review source and revise if needed. Source states that Nasal Swab was collected during the Day 28 Convalescent Visit.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:53:12
Query 'Please review source and revise if needed. Source states that Nasal Swab was collected during the Day 28 Convalescent Visit.' answered with 'entry error' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 16:27:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:27:03
User opened query 'Please review source and revise if needed. Source states that Nasal Swab was collected during the Day 28 Convalescent Visit.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:16:18
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:39:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:39:59
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	03 Nov 2020 14:39:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:12:10
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 14:12:10

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Reconciliation Requary: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 11:01:11
Query 'Per GCL Lab Reconciliation Requary: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'tracking number not available' (Site from DM).	brittany cooksey (b) (4) (b) (4)	22 Jan 2021 19:38:52
User opened query 'Per GCL Lab Reconciliation Requary: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:25:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on logline# 6, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:25:15
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on logline# 6, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'Accession Number: 1F60BYC' (Site from DM).	brittany cooksey (b) (4) (b) (4)	11 Jan 2021 21:25:43

US3302383

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response on logline# 6, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Jan 2021 03:02:27
	(b) (4), (b) (6)	06 Nov 2020 20:53:19
User entered '19 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 16:27:03
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	03 Nov 2020 14:12:10
	(b) (4)	

US3302383

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please complete the Convalescence Visit Day 28 in EDC.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 14:24:50
Query 'Please complete the Convalescence Visit Day 28 in EDC.' answered with 'updated ' (Site from CRA).	Wendy Taylor (b) (4)	29 Oct 2020 13:45:14
User opened query 'Please complete the Convalescence Visit Day 28 in EDC.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 03:09:03
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:13:43
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:54

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:13:43
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:54

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[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 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:13:43
User entered 'Clinic (Clinic)'	Wendy Taylor (b) (4)	08 Oct 2020 12:53:54

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:00:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'SICKD1'	System	08 Oct 2020 12:53:54

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27



US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '13:27'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '22 Sep 2020 13:27'	System	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '172.7' cm	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27
DataPoint set to visible.	System	08 Oct 2020 12:53:54

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '198' lb	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27
DataPoint set to visible.	System	08 Oct 2020 12:53:54

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '98.0' F	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered 'Oral (Oral)'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered empty.	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27



**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '64'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

**US3302383**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'bpm'	System	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '16'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'breaths/min'	System	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '128'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'mmHg'	System	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:21
User entered '89'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:27

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'mmHg'	System	08 Oct 2020 12:55:27



US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:39
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:37

US3302383

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:39
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:37

US3302383

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 with dates of 24SEP2020 and 26SEP2020 respectively; however Saliva Log is not completed. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:11:05
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 with dates of 24SEP2020 and 26SEP2020 respectively; however Saliva Log is not completed. Please reconcile or clarify.' answered with 'saliva log now complete' (Site from DM).	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 17:21:14
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 with dates of 24SEP2020 and 26SEP2020 respectively; however Saliva Log is not completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:32:32
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:48
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:46

US3302383

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:14:48
User entered '22 Sep 2020'	Wendy Taylor (b) (4)	08 Oct 2020 12:55:46

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per GCL Lab Reconciliation query: Swab: Per site response, "subject did not have a visit on 16NOV2020"; however, per PPD portal, swab sample was collected on 19OCT2020 at Convalescence Visit Day 28 and the same is missing in EDC. Kindly confirm if swab sample was collected on 19OCT2020, if yes, please update by initiating Covid -19 Assessment eCRF for the 19OCT2020 and updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:28:18
Query 'Per GCL Lab Reconciliation query: Swab: Per site response, "subject did not have a visit on 16NOV2020"; however, per PPD portal, swab sample was collected on 19OCT2020 at Convalescence Visit Day 28 and the same is missing in EDC. Kindly confirm if swab sample was collected on 19OCT2020, if yes, please update by initiating Covid -19 Assessment eCRF for the 19OCT2020 and updating swab data in the COVID Diagnostic Test eCRF, else clarify.' answered with 'COVID9 eCRF now added and compelled' (Site from DM).	brittany cooksey (b) (4)	06 Jan 2021 16:09:12
User opened query 'Per GCL Lab Reconciliation query: Swab: Per site response, "subject did not have a visit on 16NOV2020"; however, per PPD portal, swab sample was collected on 19OCT2020 at Convalescence Visit Day 28 and the same is missing in EDC. Kindly confirm if swab sample was collected on 19OCT2020, if yes, please update by initiating Covid -19 Assessment eCRF for the 19OCT2020 and updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:06:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 19OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 16NOV2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 05:06:45

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 19OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 16NOV2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' answered with 'subject did not have a visit on 16NOV2020' (Site from DM).	brittany cooksey (b) (4) (b) (4)	06 Jan 2021 03:10:54
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 19OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 16NOV2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:22:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:12:54
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 13:47:36



US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:12:54
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	29 Oct 2020 13:47:36

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[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 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:12:54
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	29 Oct 2020 13:47:36

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'SICKD28'	System	29 Oct 2020 13:47:36

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '08:21'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '19 Oct 2020 08:21'	System	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '68' in	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26
DataPoint set to visible.	System	29 Oct 2020 13:47:36



US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '195' lb	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26
DataPoint set to visible.	System	29 Oct 2020 13:47:36

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '98.0' F	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered empty.	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '73'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

**US3302383**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:00:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'bpm'	System	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '16'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'breaths/min'	System	29 Oct 2020 13:48:26



US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '137'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'mmHg'	System	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:13:25
User entered '91'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'mmHg'	System	29 Oct 2020 13:48:26

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:14:42
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:36

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:14:42
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	29 Oct 2020 13:48:36



US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:44:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:14:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	29 Oct 2020 13:49:03

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:44:48
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:50:58
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Lab report has been received and uploaded in source. ' (Site from DM).	Brittany Belcher (b) (4)	03 Mar 2021 20:48:19
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:57:42
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:45:40

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Accession Number: 1F60BYC' (Site from DM).	brittany cooksey (b) (4) (b) (4)	11 Jan 2021 21:23:35
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 19 OCT 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:22:21
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:28:03
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'all samples have been shipped' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 19:27:55

US3302383

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:00:55

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 08:00:54
	(b) (4), (b) (6)	05 Nov 2020 19:14:51
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	29 Oct 2020 13:49:03

US3302383

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:00:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 166, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:10:11
Query 'Per DM CLR: Per Safety Follow Up Diary Day 166, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject withdrew consent and didn't complete Day 166 per source. ' (Site from DM).	Brittany Belcher (b) (4)	26 Mar 2021 18:50:14
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 166, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:55:30
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:50:30
User signature succeeded.	Gregory Feldman (b) (4)	15 Oct 2020 21:44:42
User entered 'Yes (Y)'	brittany cooksey (b) (4)	28 Sep 2020 20:14:06

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User closed query 'When reviewing the Medical Records from Hospital stay, Monitor noticed that an Active Problem listed under the subject's discharge diagnoses was Pneumonia due to Covid-19 virus. Please add this to subject's AE Log in CRIO and EDC.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 16:15:42
Query 'When reviewing the Medical Records from Hospital stay, Monitor noticed that an Active Problem listed under the subject's discharge diagnoses was Pneumonia due to Covid-19 virus. Please add this to subject's AE Log in CRIO and EDC.' answered with 'updated. Source and EDC match.' (Site from CRA).	Brittany Belcher (b) (4)	01 Apr 2021 13:07:40
User opened query 'When reviewing the Medical Records from Hospital stay, Monitor noticed that an Active Problem listed under the subject's discharge diagnoses was Pneumonia due to Covid-19 virus. Please add this to subject's AE Log in CRIO and EDC.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:54:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:07
User entered 'USA-US087-2020-mRNA-1273-P301000001'	System	29 Sep 2020 14:40:03
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 14:40:03

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:02:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:02:10
User closed query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM, please confirm if the patient was evaluated for COVID-19 3) Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:43:49
User closed query 'PV Query: Was hypoxia a symptom of the event? If so please consider updating the event term to the underlying final diagnosis of 'Acute respiratory failure'. If to remain as Acute respiratory failure with hypoxia, please consider splitting the diagnosis into 2 separate SAE's.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:32:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM, please confirm if the patient was evaluated for COVID-19 3) Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' answered with 'Subject did not receive second vaccination. Per EPIP subject is to skip visit 2.' (Site from DM).	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 13:30:20
Query 'PV Query: Was hypoxia a symptom of the event? If so please consider updating the event term to the underlying final diagnosis of 'Acute respiratory failure'. If to remain as Acute respiratory failure with hypoxia, please consider splitting the diagnosis into 2 separate SAE's.' answered with 'records state that the principal problem was Acute respiratory failure with hypoxia. Then lists active problems with pneumonia due to COVID-19 being one of them.' (Site from Safety).	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 13:17:46
Data point term sent to Coder	System	02 Nov 2020 19:31:52
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	02 Nov 2020 19:30:58
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated' (Site from System).	brittany cooksey (b) (4) (b) (4)	02 Nov 2020 19:30:58
Data point term sent to Coder	System	02 Nov 2020 19:30:50
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	02 Nov 2020 19:30:48
User entered 'ACUTE RESPIRATORY FAILURE' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	02 Nov 2020 19:30:48
User opened query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM, please confirm if the patient was evaluated for COVID-19 3) Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:22:36



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was hypoxia a symptom of the event? If so please consider updating the event term to the underlying final diagnosis of 'Acute respiratory failure'. If to remain as Acute respiratory failure with hypoxia, please consider splitting the diagnosis into 2 separate SAE's.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:05:45
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	15 Oct 2020 23:00:29
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	15 Oct 2020 21:30:23
	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
Signature has been broken.	(b) (4)	
	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User entered 'Acute Respiratory Failure with Hypoxia.' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
	(b) (4)	
	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 20:43:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 20:43:39
Data point term sent to Coder	(b) (4)	
User entered 'Pneumonia'	System	28 Sep 2020 20:43:03
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '26 Sep 2020'	(b) (4)	
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
Signature has been broken.	brittany cooksey (b) (4)	01 Oct 2020 12:48:00
User entered 'No (N)' reason for change: New Information	brittany cooksey (b) (4)	01 Oct 2020 12:48:00
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Yes (Y)'	brittany cooksey (b) (4)	28 Sep 2020 20:42:04



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Oct 2020 21:29:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Oct 2020 21:29:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Oct 2020 12:48:00
Signature has been broken.	brittany cooksey (b) (4)	01 Oct 2020 12:48:00
User entered '28 Sep 2020' reason for change: New Information	brittany cooksey (b) (4)	01 Oct 2020 12:48:00
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	brittany cooksey (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
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	28 Sep 2020 20:47:06
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	28 Sep 2020 20:42:04
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 15:08:24
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not yet discharged' (Site from System).	brittany cooksey (b) (4)	28 Sep 2020 20:47:22
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Sep 2020 20:47:06
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		28 Sep 2020 20:47:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Sep 2020 20:47:06
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	28 Sep 2020 20:47:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Sep 2020 20:42:04
User entered '0'	brittany cooksey (b) (4)	28 Sep 2020 20:42:04



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '26 Sep 2020'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'PV Query: Please update discharge date; provided in the narrative as 28 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:15:40
Query 'PV Query: Please update discharge date; provided in the narrative as 28 Sep 2020.' answered with 'updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:02
Signature has been broken.	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User entered '28 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User opened query 'PV Query: Please update discharge date; provided in the narrative as 28 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:50:44
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	brittany cooksey (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'No (N)'	(b) (4)	
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	(b) (4)	29 Sep 2020 13:48:00
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	28 Sep 2020 20:42:04
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	28 Sep 2020 20:42:04
	(b) (4)	



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Not Related (NOT RELATED)'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: Dose Discontinuation form indicates that IP was withdrawn due to "SARS-COV-2". Please review and consider updating this field as IP was withdrawn after the End Date of this AE or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 11:54:25
Query 'Per CDM: Dose Discontinuation form indicates that IP was withdrawn due to "SARS-COV-2". Please review and consider updating this field as IP was withdrawn after the End Date of this AE or clarify. ' answered with 'entered as per query' (Site from DM).	brittany cooksey (b) (4) (b) (4)	07 Dec 2020 22:19:57
User opened query 'Per CDM: Dose Discontinuation form indicates that IP was withdrawn due to "SARS-COV-2". Please review and consider updating this field as IP was withdrawn after the End Date of this AE or clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:23:49
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 06:10:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'originally had primary reason for dosing discontinuation as AE but was queried to change it to SARS-COV-2' (Site from System).	brittany cooksey (b) (4) (b) (4)	23 Nov 2020 21:40:05
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 03:21:46
User closed query 'Per CLR CDM re-query: Thank you for your answer. Please consider updating "Dosing discontinuation" form because subject did not received second dose of treatment or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:43:54

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1273 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CLR CDM re-query: Thank you for your answer. Please consider updating "Dosing discontinuation" form because subject did not received second dose of treatment or clarify otherwise. Thank you!' answered with 'dosing disc. page now commpleted' (Site from DM).	brittany cooksey (b) (4)	03 Nov 2020 13:51:43
User opened query 'Per CLR CDM re-query: Thank you for your answer. Please consider updating "Dosing discontinuation" form because subject did not received second dose of treatment or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:56:50
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:55:26
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'Subject did not receive the 2nd vaccination. EPIP was sent 29SEP2020. Per response to EPIP visit 2 would be considered a missed visit and subject would continue to v3. Which visit 3 feel into the window of the day 28 convalescent visit. Clarification from the monitor states that the day 28 convalescent visit was to be performed with visit 3 being skipped.' (Site from DM).	brittany cooksey (b) (4)	02 Nov 2020 19:46:59
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record to match this information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:19:08

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:15:46
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated. subject did not received 2nd vaccination' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:19
Signature has been broken.	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:50:12
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	brittany cooksey (b) (4)	29 Sep 2020 13:48:00
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	brittany cooksey (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'con meds updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:50:56
DataPoint Verified.	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 14:00:22
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	(b) (4), (b) (6)	20 Oct 2020 04:22:06
User entered '1'	Gregory Feldman (b) (4) (b) (4) brittany cooksey (b) (4) (b) (4)	29 Sep 2020 13:50:05 28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:15:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'records reviewed and narrative updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:44
Signature has been broken.	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Oct 2020 21:29:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:48:41
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	brittany cooksey (b) (4)	28 Sep 2020 20:42:04



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per cDM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:32:32
User closed query 'Per CDM CLR re-query: Thank you for your updates. However, there is still missing "Supplemental oxygen" from CM form. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:32:30
Query 'Per cDM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:55:58
Query 'Per CDM CLR re-query: Thank you for your updates. However, there is still missing "Supplemental oxygen" from CM form. Please review and update or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:55:54
User opened query 'Per cDM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:21:35
User closed query 'Per DM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:21:35
User opened query 'Per CDM CLR re-query: Thank you for your updates. However, there is still missing "Supplemental oxygen" from CM form. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:17:21
User closed query 'Per DM CLR - RQ: Site's response noted. However, DECADRON, ZINC AND SUPPLEMENTAL OXYGEN were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:16:25

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1281 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = ALBUTEROL QID. However, CM frequency in CM eCRF is "PRN". Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:13:28
Query 'Per DM CLR: SAE Narrative = ALBUTEROL QID. However, CM frequency in CM eCRF is "PRN". Please review and reconcile data as appropriate.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 23:14:47
Query 'Per DM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate.	brittany cooksey (b) (4)	23 Nov 2020 23:13:49
' answered with 'con med updated' (Site from DM).		
Query 'Per DM CLR - RQ: Site's response noted. However, DECADRON, ZINC AND SUPPLEMENTAL OXYGEN were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 23:13:37
User opened query 'Per DM CLR: SAE Narrative = ALBUTEROL QID. However, CM frequency in CM eCRF is "PRN". Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:41:29
User opened query 'Per DM CLR - RQ: Site's response noted. However, DECADRON, ZINC AND SUPPLEMENTAL OXYGEN were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:41:13
User closed query 'Per DM CLR: SAE Narrative = PER RECORDS SUBJECT IS TO START MICINEX BID, TESSALON PRN, ALBUTEROL QID, DECADRON, VITAMIN C, THIAMINE AND ZINC AND SUPPLEMENTAL OXYGEN. LIPITOR IS TO BE TAKEN 40MG NIGHTLY. KLONOPIN WAS PRESCRIBED TID PRN. Please confirm if this medication were given to the patient; and if so, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:41:13
User opened query 'Per DM CLR - RQ: Site's response noted. However, this is not reocrded in the CM eCRF. Please review and record this data in the CM eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:40:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1282 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = REQUIRING 3L OXYGEN BY NASAL CANNULA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:40:05
User closed query 'Per DM CLR: SAE Narrative = RECEIVED CONVALESCENT PLASMA ON 9/26. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:28:03
User closed query 'Per DM CLR: SAE Narrative = A CHEST X-RAY WAS DONE 9/26/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:27:46
Query 'Per DM CLR: SAE Narrative = A CHEST X-RAY WAS DONE 9/26/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated form' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 16:26:07
Query 'Per DM CLR: SAE Narrative = RECEIVED CONVALESCENT PLASMA ON 9/26. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated form' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 16:25:59
Query 'Per DM CLR: SAE Narrative = REQUIRING 3L OXYGEN BY NASAL CANNULA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated form' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 16:25:53
Query 'Per DM CLR: SAE Narrative = PER RECORDS SUBJECT IS TO START MICINEX BID, TESSALON PRN, ALBUTEROL QID, DECADRON, VITAMIN C, THIAMINE AND ZINC AND SUPPLEMENTAL OXYGEN. LIPITOR IS TO BE TAKEN 40MG NIGHTLY. KLONOPIN WAS PRESCRIBED TID PRN. Please confirm if this medication were given to the patient; and if so, ensure that this is captured in the appropriate eCRF. ' answered with 'updated con med' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 16:25:47

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1283 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PER RECORDS SUBJECT IS TO START MICINEX BID, TESSALON PRN, ALBUTEROL QID, DECADRON, VITAMIN C, THIAMINE AND ZINC AND SUPPLEMENTAL OXYGEN. LIPITOR IS TO BE TAKEN 40MG NIGHTLY. KLONOPIN WAS PRESCRIBED TID PRN. Please confirm if this medication were given to the patient; and if so, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:41:54
User opened query 'Per DM CLR: SAE Narrative = A CHEST X-RAY WAS DONE 9/26/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:41:48
User opened query 'Per DM CLR: SAE Narrative = RECEIVED CONVALESCENT PLASMA ON 9/26. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:41:43
User opened query 'Per DM CLR: SAE Narrative = REQUIRING 3L OXYGEN BY NASAL CANNULA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 09:41:39
User closed query 'PV Query: It was reported that the subject went to the hospital due to low O2. Please provide the O2 saturation level.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:16:39
User closed query 'PV Query: Please report the etiology of the pneumonia (ie. bacterial, viral, covid related, etc.).' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:16:31
	(b) (4), (b) (6)	16 Oct 2020 13:16:28

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:16:19
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:16:15
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'records sent' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:37:20
Query 'PV Query: It was reported that the subject went to the hospital due to low O2. Please provide the O2 saturation level.' answered with 'records reviewed and narrative updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:31:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' answered with 'records reviewed and narrative updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:54
Query 'PV Query: Please report the etiology of the pneumonia (ie. bacterial, viral, covid related, etc.).' answered with 'records reviewed and narrative updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:50
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'records reviewed and narrative updated' (Site from Safety).	brittany cooksey (b) (4)	15 Oct 2020 21:30:46

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS CONTACTED TODAY FOR DAY 7 AND HE REPORTED THAT HE WAS ADMITTED TO THE HOSPITAL ON 9/26/2020. HE STATED THAT HIS PREVIOUSLY REPORTED SYMPTOMS HAVE GOTTEN BETTER. HE WENT TO THE HOSPITAL DUE TO HIS OXYGEN LEVEL BEING LOW ON 9/26/2020. SUBJECT CONFIRMED WITH ME VIA PHONE THAT HE WAS DIAGNOSED WITH PNEUMONIA. MEDICAL RECORDS TO BE REQUESTED ONCE SUBJECT IS DISCHARGED FROM HOSPITAL AND IS ABLE TO COME TO SITE TO SIGN RECORD RELEASE FORM. UPDATES WILL BE MADE AS RECORDS ARE RECEIVED AND REVIEWED. UPDATE: 10/1/2020 SUBJECT REPORTED THAT HE WAS DISCHARGED ON EVENING OF 9/28/2020. RECORDS RELEASE FORM HAS NOW BEEN SIGNED BY SUBJECT AND RECORDS HAVE BEEN REQUESTED TO CONFIRM ALL INFORMATION FROM HOSPITALIZATION. Medical records were received and reviewed 10/15/2020. Subjects discharge diagnosis notes the principal problem was Acute respiratory failure with hypoxia with active problems of hyperlipidemia, Pneumonia due to COVID-19 and Tic disorder. Subject presented to ER with acute shortness of breath, found to be hypoxic requiring 3L oxygen by nasal cannula. Patient was afebrile and tachycardic on arrival, satting 89% on room air, improved on supplemental oxygen. He was consent for treatment with remdesivir and coalescent plasma. He received 2 days of remdesivir 9/26-9/27 and received convalescent plasma on 9/26. A chest x-ray was done 9/26/2020 showing bilateral infiltrates consistent with infection. Per records subject is to start Micinex BID, Tessalon PRN, Albuterol QID, Decadron, vitamin C, thiamine and Zinc and supplemental oxygen. Lipitor is to be taken 40mg nightly. Klonopin was prescribed TID PRN. Subject was discharged 9/28/2020 and was able to be weaned down to room air with saturations in the high 90s.' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Oct 2020 21:29:51

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1286 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject went to the hospital due to low O2. Please provide the O2 saturation level.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:11:14
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:52:05
User opened query 'PV Query: Please report the etiology of the pneumonia (ie. bacterial, viral, covid related, etc.).' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:51:30
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:49:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:49:11
Signature has been broken.	brittany cooksey (b) (4) (b) (4)	01 Oct 2020 12:48:00



US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS CONTACTED TODAY FOR DAY 7 AND HE REPORTED THAT HE WAS ADMITTED TO THE HOSPITAL ON 9/26/2020. HE STATED THAT HIS PREVIOUSLY REPORTED SYMPTOMS HAVE GOTTEN BETTER. HE WENT TO THE HOSPITAL DUE TO HIS OXYGEN LEVEL BEING LOW ON 9/26/2020. SUBJECT CONFIRMED WITH ME VIA PHONE THAT HE WAS DIAGNOSED WITH PNEUMONIA. MEDICAL RECORDS TO BE REQUESTED ONCE SUBJECT IS DISCHARGED FROM HOSPITAL AND IS ABLE TO COME TO SITE TO SIGN RECORD RELEASE FORM. UPDATES WILL BE MADE AS RECORDS ARE RECEIVED AND REVIEWED. UPDATE: 10/1/2020 Subject reported that he was discharged on evening of 9/28/2020. Records release form has now been signed by subject and records have been requested to confirm all information from hospitalization.' reason for change: Data Entry Error User signature succeeded.	brittany cooksey (b) (4)	01 Oct 2020 12:48:00
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Gregory Feldman (b) (4)	29 Sep 2020 13:50:05
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 20:47:06
User entered 'Subject was contacted today for Day 7 and he reported that he was admitted to the hospital on 9/26/2020. He stated that his previously reported symptoms have gotten better. He went to the hospital due to his oxygen level being low on 9/26/2020. Subject confirmed with me via phone that he was diagnosed with Pneumonia. Medical records to be requested once subject is discharged from hospital and is able to come to site to sign record release form. Updates will be made as records are received and reviewed.' reason for change: Data Entry Error	brittany cooksey (b) (4)	28 Sep 2020 20:47:06
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Sep 2020 20:42:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1288 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	28 Sep 2020 20:42:04

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	28 Sep 2020 20:42:04

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	28 Sep 2020 20:42:04

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '0'	System	28 Sep 2020 20:42:04

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:55:52
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:55:50
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:55:44
User entered 'USA-US087-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	01 Oct 2020 16:55:40

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:39:33
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 11:23:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 11:23:00
User closed query 'PV Query: Thank you for updating event term to "COVID-19 positive." Please consider updating event term to "COVID-19."' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:23:04
Data point term sent to Coder	System	02 Nov 2020 19:51:22
Query 'PV Query: Thank you for updating event term to "COVID-19 positive." Please consider updating event term to "COVID-19."' answered with 'updated' (Site from Safety).	brittany cooksey (b) (4)	02 Nov 2020 19:50:45
DataPoint Un-verified.	brittany cooksey (b) (4)	02 Nov 2020 19:50:37
Coding entries removed.	brittany cooksey (b) (4)	02 Nov 2020 19:50:37
User entered 'COVID-19' reason for change: Data Entry Error	brittany cooksey (b) (4)	02 Nov 2020 19:50:37
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'PV Query: Thank you for updating event term to "COVID-19 positive." Please consider updating event term to "COVID-19."' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:08:34
User closed query 'PV Query: Please consider updating event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:38
User coded data point as SOC: Investigations, HLT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 13:58:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 13:58:39

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1294 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Oct 2020 13:20:51
Query 'PV Query: Please consider updating event term to COVID-19.' answered with 'updated ' (Site from Safety).	Wendy Taylor (b) (4)	06 Oct 2020 13:20:04
Coding entries removed.	Wendy Taylor (b) (4)	06 Oct 2020 13:19:57
User entered 'COVID-19 POSITIVE' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Oct 2020 13:19:57
User opened query 'PV Query: Please consider updating event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:27
User coded data point as SOC: Investigations, HLT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 22:23:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 22:23:35
Data point term sent to Coder	System	30 Sep 2020 22:23:22
User entered 'COVID positive'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03



US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:39:30
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:55:00
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	02 Nov 2020 19:50:50
DataPoint Un-verified.	brittany cooksey (b) (4)	02 Nov 2020 19:50:37
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	02 Nov 2020 19:50:37
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:16:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'PV Query: The start of the event should be when the subject began to experience symptoms. Please consider updating the event start date to onset date of symptoms, 22 Sep 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:24:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:50:22
Query 'PV Query: The start of the event should be when the subject began to experience symptoms. Please consider updating the event start date to onset date of symptoms, 22 Sep 2020.' answered with 'updated per quert' (Site from Safety).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 21:33:17
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 21:33:09
User entered '22 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 21:33:09
User opened query 'PV Query: The start of the event should be when the subject began to experience symptoms. Please consider updating the event start date to onset date of symptoms, 22 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 17:30:31
User closed query 'PV Query: Per the discharge summary the subject tested positive for COVID-19 on 18 Sep 2020. Please confirm.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:21:17
User closed query 'PV Query: The start date of the event is reported as 29 Sep 2020; however, the COVID-19 assessment log reports the symptom of mild chills on 22 Sep 2020. Please confirm the event start date or updated if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:21:00
User closed query 'Per MM, please confirm if the subject received the second dose of IP before the start date of the event.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:54:40

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The start date of the event is reported as 29 Sep 2020; however, the COVID-19 assessment log reports the symptom of mild chills on 22 Sep 2020. Please confirm the event start date or updated if applicable.' answered with 'positive COVID results were received 9/29/2020 which is the start date listed for AE. ' (Site from Safety).	brittany cooksey (b) (4)	02 Nov 2020 20:26:22
Query 'Per MM, please confirm if the subject received the second dose of IP before the start date of the event.' answered with 'second vaccine was not received due to illness visits occurring during window of visit 2. EPIP confirms that subject will skip visit 2 and proceed to visit 3. Visit 3 fell into the window of the day 28 convalescent visit. Per monitor confirmation I was to complete the day 28.' (Site from DM).	brittany cooksey (b) (4)	02 Nov 2020 20:04:18
Query 'PV Query: Per the discharge summary the subject tested positive for COVID-19 on 18 Sep 2020. Please confirm.' answered with 'subject never reported testing positive for COVID prior to illness day1. Start date listed is day that results came back showing subject had tested positive. ' (Site from Safety).	brittany cooksey (b) (4)	02 Nov 2020 20:02:17
User opened query 'Per MM, please confirm if the subject received the second dose of IP before the start date of the event.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:36:30
User opened query 'PV Query: Per the discharge summary the subject tested positive for COVID-19 on 18 Sep 2020. Please confirm.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:04:57
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'PV Query: The start date of the event is reported as 29 Sep 2020; however, the COVID-19 assessment log reports the symptom of mild chills on 22 Sep 2020. Please confirm the event start date or updated if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:02:45
Query 'PV Query: The start date of the event is reported as 29 Sep 2020; however, the COVID-19 assessment log reports the symptom of mild chills on 22 Sep 2020. Please confirm the event start date or updated if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:44

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: The start date of the event is reported as 29 Sep 2020; however, the COVID-19 assessment log reports the symptom of mild chills on 22 Sep 2020. Please confirm the event start date or updated if applicable.' (Site from Safety). User entered '29 Sep 2020'	(b) (4), (b) (6) (b) (4)	05 Oct 2020 12:55:11
	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	30 Sep 2020 22:23:03



US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:41:22
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:35:00
DataPoint Un-verified.	brittany cooksey (b) (4)	02 Nov 2020 20:35:00
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	02 Nov 2020 20:35:00
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:27:07
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:41:20
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:21:42
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:35:46
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Nov 2020 20:35:46
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	brittany cooksey (b) (4)	02 Nov 2020 20:35:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:27:07
DataPoint Un-verified.	brittany cooksey (b) (4)	02 Nov 2020 20:27:07
User entered '29 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	02 Nov 2020 20:27:07
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:47

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	05 Oct 2020 12:52:43
	brittany cooksey (b) (4)	30 Sep 2020 22:23:03
	(b) (4)	

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered 'No (N)'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03



US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03



US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:23:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	brittany cooksey (b) (4)	30 Sep 2020 22:23:33
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:03
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:23:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	brittany cooksey (b) (4)	30 Sep 2020 22:23:33
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:03
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded. ' (Site from DM). Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded. ' answered with 'subject was Dx with both during hospital stay' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:14:51
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded. ' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 19:23:38
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 16:01:44
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:10:45
Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'original entry was AE but query requested it be changes to SARS-COV-2' (Site from DM).	brittany cooksey (b) (4) (b) (4)	24 Nov 2020 06:10:41
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'original entry was AE but query requested it be changes to SARS-COV-2' (Site from System).	brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:16:46
		23 Nov 2020 23:16:43

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 03:21:46
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:42:45
	(b) (4), (b) (6)	05 Nov 2020 15:42:03
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:23:54
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	brittany cooksey (b) (4)	03 Nov 2020 14:01:14
	(b) (4)	
	brittany cooksey (b) (4)	03 Nov 2020 14:01:05
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error DataPoint Verified.	brittany cooksey (b) (4)	03 Nov 2020 14:01:05
	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:02:16
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:51

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:44
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:23:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	brittany cooksey (b) (4)	30 Sep 2020 22:23:33
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:03
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:01
User closed query 'Per CDM CLR re-query: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:10:51
Query 'Per CDM CLR re-query: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 23:17:04
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 23:16:57
User entered '0' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 23:16:57
User opened query 'Per CDM CLR re-query: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:54:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field.	(b) (4), (b) (6)	17 Nov 2020 06:54:33
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field.	brittany cooksey (b) (4)	17 Nov 2020 02:54:45
' answered with 'entered is correct' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (i.e., Convalescent Plasma) recorded that matches this AE during this timeframe. Please review and update this field.'	(b) (4), (b) (6)	17 Nov 2020 00:43:08

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1326 of 1921

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Sep 2020 22:23:33
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	30 Sep 2020 22:23:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	30 Sep 2020 22:23:03
User entered '0'	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 22:23:03



US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:03
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:20:03
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	07 Dec 2020 22:19:24
DataPoint Un-verified.	brittany cooksey (b) (4)	07 Dec 2020 22:19:12
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	07 Dec 2020 22:19:12
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 02:33:08
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:06
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 23:16:57
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 23:16:57
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered '0'	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:12
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:21:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	brittany cooksey (b) (4)	02 Nov 2020 20:36:09
DataPoint Un-verified.	brittany cooksey (b) (4)	02 Nov 2020 20:35:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	brittany cooksey (b) (4)	02 Nov 2020 20:35:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:23
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:53:09
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:24:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:24:12

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	brittany cooksey (b) (4)	30 Sep 2020 22:24:12
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:23:03
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
User entered empty.	brittany cooksey (b) (4)	30 Sep 2020 22:23:03

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:49:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:37:08
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.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:36:22
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:43
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:34

US3302383

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:47:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:47:02
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.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 13:46:59
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including imaging, additional covid testing, and cultures). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:53:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:53:47
User entered empty.	brittany cooksey (b) (4) (b) (4)	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '0'	System	30 Sep 2020 22:23:03



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	30 Sep 2020 22:23:03

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 22:23:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 22:23:59
Data point term sent to Coder	System	14 Jan 2021 22:23:33
User entered 'worsening Hyperlipidemia'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:42
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:46
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 22:23:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 22:23:30
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	14 Jan 2021 22:23:30
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 22:23:24
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:48
User entered 'No (N)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:51
User entered '29 Sep 2020'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:16:53
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:00
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 07:14:14
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'entered is correct' (Site from DM).	brittany cooksey (b) (4)	26 Jan 2021 21:13:55
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:03:20
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:02
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:04
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:11
User entered 'No (N)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24



US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

US3302383

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:00:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered 'Not Applicable (NOT APPLICABLE)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered 'l'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered '0'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:17:41
User entered empty.	brittany cooksey (b) (4)	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '0'	System	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	14 Jan 2021 22:23:24

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
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)	06 Apr 2021 12:47:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:47:50
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
Data point term sent to Coder	System	01 Apr 2021 13:07:35
User entered 'Pneumonia (due to Covid-19)'	Brittany Belcher (b) (4)  (b) (4)	01 Apr 2021 13:07:01



US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'No (N)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '22 Sep 2020'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'No (N)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:09:20
User closed query 'Please review source and revise if needed. Source states that end date of AE was 29Sep2020.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 19:08:51
Query 'Please review source and revise if needed. Source states that end date of AE was 29Sep2020.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	01 Apr 2021 17:54:49
DataPoint Un-verified.	Brittany Belcher (b) (4)	01 Apr 2021 17:54:33
User entered '29 Sep 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	01 Apr 2021 17:54:33
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User opened query 'Please review source and revise if needed. Source states that end date of AE was 29Sep2020.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:35:52
User entered '22 Sep 2020'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'No (N)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01



US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01



US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Not Applicable (NOT APPLICABLE)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'l'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered '0'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:36:23
User entered empty.	Brittany Belcher (b) (4)	01 Apr 2021 13:07:01

**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '0'	System	01 Apr 2021 13:07:01



**US3302383**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered 'I'	System	01 Apr 2021 13:07:01

US3302383

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:00:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per ETRTR: Please add Medication dosed at Hospitalization for SAE "Pneumonia", thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 03:49:25
Query 'Per ETRTR: Please add Medication dosed at Hospitalization for SAE "Pneumonia", thanks.' answered with 'con meds up to date' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 17:20:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:53:38
User opened query 'Per ETRTR: Please add Medication dosed at Hospitalization for SAE "Pneumonia", thanks.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 20:15:29
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:52:38

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Please add all ConMeds given to the subject during their Hospital Stay for the SAE.' (Site from CRA).	(b) (4)	
Query 'Please add all ConMeds given to the subject during their Hospital Stay for the SAE.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 03:46:16
User opened query 'Please add all ConMeds given to the subject during their Hospital Stay for the SAE.' (Site from CRA).	brittany cooksey (b) (4)	03 Nov 2020 14:02:06
DataPoint Verified.	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	20 Oct 2020 15:26:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
Data point term sent to Coder	Coder Import (b) (4)	27 Aug 2020 17:43:33
User entered 'citalopram'	(b) (4)	
	System	26 Aug 2020 15:53:48
	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'tourette's syndrome'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '40'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'mg (mg)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'un UNK 2008'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:10

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:53:10

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:53:10

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	26 Aug 2020 15:53:10

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
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)	26 Aug 2020 15:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:56:51
Data point term sent to Coder	System	26 Aug 2020 15:53:48
User entered 'montelaukast'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'seasonal allergies'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '10'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'mg (mg)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'un UNK 2018'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:53:42

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:53:42

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	26 Aug 2020 15:53:42

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
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)	27 Aug 2020 17:43:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:43:26
Data point term sent to Coder	System	26 Aug 2020 15:54:50
User entered 'clonazepam'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'tourette's syndrome'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:46:55
User closed query 'Per CDM: Please review if this "Dose per administration" is entered correctly, because at the moment it is ".5". Please review and correct or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:25:57
Query 'Per CDM: Please review if this "Dose per administration" is entered correctly, because at the moment it is ".5". Please review and correct or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 17:14:07
DataPoint Un-verified.	Brittany Belcher (b) (4)	29 Oct 2020 17:14:03
User entered '0.5' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 17:14:03
User opened query 'Per CDM: Please review if this "Dose per administration" is entered correctly, because at the moment it is ".5". Please review and correct or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:20:22
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '.5'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'mg (mg)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'three times daily (TID)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'un UNK 2008'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:15

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '3'	System	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:54:15



**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	26 Aug 2020 15:54:15

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:56:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:56:50
Data point term sent to Coder	System	26 Aug 2020 15:54:50
User entered 'atorvastatin'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'hyperlipidemia'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '5'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'mg (mg)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'every other day (QOD)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered '0'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered empty.	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:54:33
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:45



US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	26 Aug 2020 15:54:45

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '2'	System	26 Aug 2020 15:54:45

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	26 Aug 2020 15:54:45

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per MM: Please clarify whether or not this CM was given as part of a clinical trial.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 11:48:16
Query 'Per MM: Please clarify whether or not this CM was given as part of a clinical trial.' answered with 'given for SAE' (Site from DM).	brittany cooksey (b) (4)	07 Dec 2020 22:18:13
User opened query 'Per MM: Please clarify whether or not this CM was given as part of a clinical trial.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:42:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
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)	03 Nov 2020 15:05:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:24
Data point term sent to Coder	System	03 Nov 2020 13:58:57
User entered 'Remdesivir'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'No (N)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'SAE - acute respiratory failure'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered '100'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'mg (mg)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'once daily (QD)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'Intravenous (INTRAVENOUS)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered empty.	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered '26 Sep 2020'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered '0'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'No (N)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per CDM: AE end date and hospital discharge date is marked as 28Sep2020, however here medication end date is 27Sep2020. Please review and update or confirm that medication end date is 27Sep2020. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:10:52
Query 'Per CDM: AE end date and hospital discharge date is marked as 28Sep2020, however here medication end date is 27Sep2020. Please review and update or confirm that medication end date is 27Sep2020. Thank you!' answered with 'entered is correct' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 16:23:03
User opened query 'Per CDM: AE end date and hospital discharge date is marked as 28Sep2020, however here medication end date is 27Sep2020. Please review and update or confirm that medication end date is 27Sep2020. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:52:42
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered '27 Sep 2020'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 03:48:43
User entered 'No (N)'	brittany cooksey (b) (4)	03 Nov 2020 13:58:04

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	03 Nov 2020 13:58:04

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	03 Nov 2020 13:58:04

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:57:49
Data point term sent to Coder	System	15 Nov 2020 23:57:35
Coding entries removed.	marsha gossett (b) (4)	15 Nov 2020 23:57:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:37:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:37:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:07:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:07:18

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1501 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Nov 2020 16:06:48
User entered 'mucinex'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:02:55
User closed query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). Query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' answered with 'source updated. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:02:43
User opened query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). User signature succeeded.	Brittany Belcher (b) (4)	31 Mar 2021 21:27:59
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:32:46
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:47:54
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	07 Dec 2020 22:20:18
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:44:18

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:08:36
Query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' answered with 'CORRECTED' (Site from DM).	marsha gossett (b) (4)	15 Nov 2020 23:57:23
DataPoint Un-verified.	(b) (4)	
	marsha gossett (b) (4)	15 Nov 2020 23:57:17
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	15 Nov 2020 23:57:17
User opened query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:39:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'SAE'	(b) (4)	
	brittany cooksey (b) (4)	06 Nov 2020 16:05:50
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '1200'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'mg (mg)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'twice daily (BID)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '06 Oct 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:05:50

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '2'	System	06 Nov 2020 16:05:50

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:05:50



**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	06 Nov 2020 16:05:50

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:57:49
Data point term sent to Coder	System	15 Nov 2020 23:57:35
Coding entries removed.	marsha gossett (b) (4)	15 Nov 2020 23:57:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:09:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:09:18
Data point term sent to Coder	System	06 Nov 2020 16:07:49
User entered 'tessalon'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:03:35
User closed query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). Query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' answered with 'Source updated. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:03:20
User opened query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). User signature succeeded.	Brittany Belcher (b) (4)	31 Mar 2021 21:29:00
User closed query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). Query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' answered with 'CORRECTED' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:33:18
User entered 'COVID-19' reason for change: Data Entry Error	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User opened query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 13:08:40
User entered 'SAE'	marsha gossett (b) (4)	15 Nov 2020 23:57:38
	(b) (4)	15 Nov 2020 23:57:33
	marsha gossett (b) (4)	15 Nov 2020 23:57:33
	(b) (4)	15 Nov 2020 23:57:33
	(b) (4), (b) (6)	11 Nov 2020 11:39:07
	(b) (4), (b) (6)	10 Nov 2020 21:52:24
	brittany cooksey (b) (4)	06 Nov 2020 16:07:40
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '100'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'mg (mg)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'as needed (PRN)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:04:06
User closed query 'Stop date is not listed in Source for this Con Medication, please review and update source if needed so Monitor can SDV data.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:03:56
Query 'Stop date is not listed in Source for this Con Medication, please review and update source if needed so Monitor can SDV data.' answered with 'Source updated and now matches EDC. ' (Site from CRA).	Brittany Belcher (b) (4)	31 Mar 2021 21:30:05
User opened query 'Stop date is not listed in Source for this Con Medication, please review and update source if needed so Monitor can SDV data.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:34:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
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) (6)	14 Jan 2021 07:13:33
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).	brittany cooksey (b) (4)	13 Jan 2021 23:26:18
DataPoint Un-verified.	brittany cooksey (b) (4)	13 Jan 2021 23:26:10
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 23:26:10
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)	12 Jan 2021 16:42:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1533 of 1921

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:04:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	13 Jan 2021 23:26:10
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	13 Jan 2021 23:26:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:07:40
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:07:40



**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	06 Nov 2020 16:07:40

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	06 Nov 2020 16:07:40

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	06 Nov 2020 16:07:40

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 23:59:49
Data point term sent to Coder	System	15 Nov 2020 23:58:37
Coding entries removed.	marsha gossett (b) (4)	15 Nov 2020 23:57:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:59:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:59:27
Data point term sent to Coder	System	06 Nov 2020 16:09:53
User entered 'albuterol'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:04:56
User closed query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). Query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' answered with 'Source updated and now matches EDC. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:04:44
User opened query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). User signature succeeded.	Brittany Belcher (b) (4)	31 Mar 2021 21:30:59
User closed query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). Query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' answered with 'CORRECTED' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:34:44
User entered 'COVID-19' reason for change: Data Entry Error	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User opened query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 13:08:44
User entered 'SAE'	marsha gossett (b) (4)	15 Nov 2020 23:57:52
	(b) (4)	15 Nov 2020 23:57:47
	marsha gossett (b) (4)	15 Nov 2020 23:57:47
	(b) (4)	15 Nov 2020 23:57:47
	(b) (4), (b) (6)	11 Nov 2020 11:39:15
	(b) (4), (b) (6)	10 Nov 2020 21:52:24
	brittany cooksey (b) (4)	06 Nov 2020 16:09:14
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '90'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'ug (ug)'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:05:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 23:15:21
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 23:15:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'as needed (PRN)'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:05:25
DataPoint Un-verified.	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
Signature has been broken.	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
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) (6)	14 Jan 2021 07:13:39
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 'continued use as needed' (Site from DM).	brittany cooksey (b) (4)	13 Jan 2021 23:28:17
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)	12 Jan 2021 16:43:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:04:44
DataPoint Verified.	(b) (4)	01 Apr 2021 17:24:43
DataPoint Un-verified.	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
Signature has been broken.	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
User entered '29 Sep 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	31 Mar 2021 21:32:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:09:14

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '4'	System	23 Nov 2020 23:15:21
User entered empty.	System	06 Nov 2020 16:09:14

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	23 Nov 2020 23:15:21
User entered empty.	System	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	23 Nov 2020 23:15:21
User entered empty.	System	06 Nov 2020 16:09:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:27:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 16:27:18
Data point term sent to Coder	System	06 Nov 2020 16:11:57
User entered 'vitamin C'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'supplement'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'l'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'tablet (TABLET)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'once daily (QD)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:11:23

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:11:23

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:11:23

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	06 Nov 2020 16:11:23

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:03:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:03:12
Data point term sent to Coder	System	15 Nov 2020 23:58:36
Coding entries removed.	marsha gossett (b) (4)	15 Nov 2020 23:58:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:36:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:36:28
Data point term sent to Coder	System	06 Nov 2020 16:20:13
User entered 'thiamine'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:28:38
User closed query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). Query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' answered with 'Source is updated and now matches EDC. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 17:28:27
User opened query 'Indication was changed from SAE Acute Respiratory Failure to Covid-19 per query by CDM. If change is correct, please revise indication/reason for medication in source, so Monitor can SDV the data.' (Site from CRA). User signature succeeded.	Brittany Belcher (b) (4)	31 Mar 2021 21:34:11
User closed query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). Query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' answered with 'CORRECTED' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:35:57
User entered 'COVID-19' reason for change: Data Entry Error	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User opened query 'Per CDM: Please consider entering proper indication instead of SAE. Thank you!' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 13:08:53
User entered 'SAE'	marsha gossett (b) (4)	15 Nov 2020 23:58:15
	(b) (4)	15 Nov 2020 23:58:09
	marsha gossett (b) (4)	15 Nov 2020 23:58:09
	(b) (4)	15 Nov 2020 23:58:09
	(b) (4), (b) (6)	11 Nov 2020 11:39:24
	(b) (4), (b) (6)	10 Nov 2020 21:52:24
	brittany cooksey (b) (4)	06 Nov 2020 16:19:14
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:13:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'entered is correct and all information that is available' (Site from DM).	brittany cooksey (b) (4) (b) (4)	13 Jan 2021 23:28:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:43:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'I'	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'tablet (TABLET)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'once daily (QD)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:19:14

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:19:14



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	06 Nov 2020 16:19:14

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 12:01:30
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'AE added' (Site from DM).	brittany cooksey (b) (4) (b) (4)	14 Jan 2021 22:22:16
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:44:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 12:32:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 12:32:41
Data point term sent to Coder Coding entries removed.	System Wendy Taylor (b) (4)	23 Dec 2020 12:31:31 23 Dec 2020 12:30:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:55:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:55:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:39:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 16:39:24
Data point term sent to Coder User entered 'lipitor'	System brittany cooksey (b) (4) (b) (4)	06 Nov 2020 16:23:17 06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:09
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please review the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Medical history eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 05:59:11
Query 'Per DM CLR: Please review the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Medical history eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	23 Dec 2020 12:31:00
DataPoint Un-verified.	Wendy Taylor (b) (4)	23 Dec 2020 12:30:53
User entered 'hyperlipidemia' reason for change: Data Entry Error	Wendy Taylor (b) (4)	23 Dec 2020 12:30:53
User opened query 'Per DM CLR: Please review the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Medical history eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 04:37:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'cholesterol'	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '40'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'mg (mg)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:22:28



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'once daily (QD)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Oral (ORAL)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '29 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:22:28



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:52:24
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 16:22:28

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:22:28

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	06 Nov 2020 16:22:28

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	06 Nov 2020 16:22:28

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 22:03:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 22:03:03
Data point term sent to Coder	System	23 Nov 2020 22:02:12
User entered 'Zinc'	brittany cooksey (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:32
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:46:42
User closed query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:46:41
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	07 Dec 2020 22:21:02
Query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	07 Dec 2020 22:20:58
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	07 Dec 2020 22:20:52
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:13:56
User opened query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:30:38
User entered 'No (N)'	brittany cooksey (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'supplement'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 12:01:40
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'listed is what was provided. dose is unk' (Site from DM).	brittany cooksey (b) (4) (b) (4)	14 Jan 2021 22:27:17
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:45:24
User entered 'I'	brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'tablet (TABLET)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 22:01:56
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'once daily (QD)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:48
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 22:01:56
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Oral (ORAL)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '29 Sep 2020'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 22:01:56

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	23 Nov 2020 22:01:56

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	23 Nov 2020 22:01:56

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	23 Nov 2020 22:01:56

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:52:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:52:15
Data point term sent to Coder	System	23 Nov 2020 23:13:45
User entered 'Decadron'	brittany cooksey (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'AE - acute respiratory failure'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0.75'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'mg (mg)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 23:12:57
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'twice daily (BID)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 23:12:57
	(b) (4)	

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Oral (ORAL)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:48
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	23 Nov 2020 23:12:57
	(b) (4)	



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (28SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:09:09
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (28SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'to be taken after discharge' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 13:32:33
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (28SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:15:23
User entered '29 Sep 2020'	brittany cooksey (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '06 Oct 2020'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	23 Nov 2020 23:12:57

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '2'	System	23 Nov 2020 23:12:57

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '1'	System	23 Nov 2020 23:12:57

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered '804 (804)'	System	23 Nov 2020 23:12:57



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 22:36:05
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 Nov 2020 22:36:05
Data point term sent to Coder	System	24 Nov 2020 19:55:51
User entered 'Oxygen'	(b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'AE (acute respiratory failure)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '3'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:21
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:25
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'L/min'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41



US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:38:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:41

**US3302383**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	24 Nov 2020 19:55:41



US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	24 Nov 2020 19:55:41

US3302383

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:00:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User entered empty.	System	24 Nov 2020 19:55:41

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:00:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Un-verified.	brittany cooksey (b) (4)	06 Nov 2020 16:23:36
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 16:23:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:48:34
User entered 'No (N)'	Brittany Belcher (b) (4)	26 Aug 2020 15:54:50

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:24:12

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 09:51:46
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' answered with 'this was added per previoud queries' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 19:24:25
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:01:39
User entered 'convalescent plasma'	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 16:24:12

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Adverse Event (AE)'	brittany cooksey (b) (4)	06 Nov 2020 16:24:12

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:00:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:24:12

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '26 Sep 2020'	brittany cooksey (b) (4)	06 Nov 2020 16:24:38



US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Chest X-Ray'	brittany cooksey (b) (4)	06 Nov 2020 16:24:38

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered 'Adverse Event (AE)'	brittany cooksey (b) (4)	06 Nov 2020 16:24:38

US3302383

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:00:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 16:24:38

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'Visit 2 Day 29 (VISIT2)'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'l'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '24 Sep 2020'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'l'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered empty.	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User closed query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' (Site from System).	System	05 Nov 2020 16:31:22
Query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' answered by data change (Site from System).	System	05 Nov 2020 16:31:22
User opened query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' (Site from System).	System	05 Nov 2020 16:30:31
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	05 Nov 2020 16:31:22
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 17:00:55

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:30:31

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'Visit 3 Day 57 (VISIT3)'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'l'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '19 Oct 2020'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'l'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered empty.	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered 'l'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11



US3302383

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 09 Jun 2021 17:00:55

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:09:47
User entered '0'	brittany cooksey (b) (4)	05 Nov 2020 16:34:11

**US3302383**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 09 Jun 2021 17:00:55**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:08:18
User entered '29 Sep 2020'	brittany cooksey (b) (4)	03 Nov 2020 13:51:07

US3302383

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:55

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:13:31
User closed query 'Per CDM re-query: For "Primary reason for dosing discontinuation" consider selecting "SARS-COV-2" instead of AE. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:22:39
Query 'Per CDM re-query: For "Primary reason for dosing discontinuation" consider selecting "SARS-COV-2" instead of AE. Thank you!" answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 03:21:53
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 03:21:46
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 03:21:46
User opened query 'Per CDM re-query: For "Primary reason for dosing discontinuation" consider selecting "SARS-COV-2" instead of AE. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:15:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:08:18
User entered 'AE (specify) (ADVERSE EVENT)'	brittany cooksey (b) (4)	03 Nov 2020 13:51:07

US3302383

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:55

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:13:32
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:25:10
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 03:22:15
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 03:22:15
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details. Thank you.' answered with 'updated per query' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 03:22:04
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 03:21:46
User entered '2' reason for change: Data Entry Error	brittany cooksey (b) (4)	23 Nov 2020 03:21:46
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:37:59
User closed query 'Per CDM re-query: Please consider updating "Primary reason for dosing discontinuation" to Due to SARS-COV-2 or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:09:03
Query 'Per CDM re-query: Please consider updating "Primary reason for dosing discontinuation" to Due to SARS-COV-2 or clarify otherwise. Thank you!' answered with 'WORD POSITIVE REMOVED PER QUERY' (Site from DM).	marsha gossett (b) (4)	15 Nov 2020 23:59:14
DataPoint Un-verified.	marsha gossett (b) (4)	15 Nov 2020 23:59:06

US3302383

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:55

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'SARS-COV-2' reason for change: Data Entry Error	marsha gossett (b) (4) (b) (4)	15 Nov 2020 23:59:06
User opened query 'Per CDM re-query: Please consider updating "Primary reason for dosing discontinuation" to Due to SARS-COV-2 or clarify otherwise. Thank you!' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 11:32:06
User closed query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' (Site from DM). Query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Wendy Taylor (b) (4) (b) (4), (b) (6) Wendy Taylor (b) (4) (b) (4), (b) (6)	06 Nov 2020 20:02:23 06 Nov 2020 20:02:15 06 Nov 2020 20:02:15
User entered 'SARS-COV-2 positive' reason for change: Data Entry Error	Wendy Taylor (b) (4) (b) (4), (b) (6)	06 Nov 2020 16:45:33
User opened query 'Per CDM: "other specify' is entered as "SARS COV 2 Positive", however "Primary reason for dosing discontinuation is not "Due to SARS-COV-2". Please review and consider updating or comment accordingly. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 19:08:18
User entered 'COVID-19'	brittany cooksey (b) (4) (b) (4)	03 Nov 2020 13:51:07

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered '19 Oct 2020'	(b) (4)	24 Mar 2021 19:27:16

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4) Brittany Belcher (b) (4)	24 Mar 2021 19:27:16

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered 'Subject with drew consent after completing illness visits.'	Brittany Belcher (b) (4)	24 Mar 2021 19:27:16



US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered empty.	(b) (4)	24 Mar 2021 19:27:16

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered empty.	(b) (4)	24 Mar 2021 19:27:16

US3302383

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:55

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered empty.	(b) (4)	24 Mar 2021 19:27:16

**US3302383**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 17:00:55**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:40:36
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:23:15
User entered empty.	(b) (4)	24 Mar 2021 19:27:16

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
User entered '29/Sep/2020 10:40'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
User entered '01/Oct/2020 12:56'	System	01 Oct 2020 16:56:23

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:47:14
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 16:56:23



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
User entered '07/Oct/2020 13:47'	System	07 Oct 2020 13:47:24

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 13:16:48
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 13:47:24

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03



US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
User entered '16/Oct/2020 13:16'	System	16 Oct 2020 13:16:58

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:32:45
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 13:16:58

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:34:43
User entered '03/Nov/2020 11:32'	System	03 Nov 2020 16:32:59

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:34:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 14:24:03
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 16:32:59

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:35:53
User entered '04/Nov/2020 09:24'	System	04 Nov 2020 14:24:15

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 18:26:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:35:55
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 14:24:15



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'USA-US087-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Yes (Y)'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'No (N)'	System	29 Sep 2020 14:40:03



US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Gregory'	System	29 Sep 2020 14:40:03

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Feldman'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '141 Harold Fleming Court'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered 'Spartanburg'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:40:22
User entered '29303'	System	29 Sep 2020 14:40:03

**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:55**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 14:30:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 16:56:10
User entered 'US'	System	29 Sep 2020 14:40:28

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
User entered '7'	System	11 Nov 2020 18:27:16
User entered '6'	System	04 Nov 2020 14:24:15
User entered '5'	System	03 Nov 2020 16:32:59
User entered '4'	System	16 Oct 2020 13:16:58
User entered '3'	System	07 Oct 2020 13:47:24
User entered '2'	System	01 Oct 2020 16:56:23
User entered '1'	System	29 Sep 2020 14:40:28



**US3302383**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:00:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:20:06
User entered '11/Nov/2020 18:27'	System	11 Nov 2020 18:27:16

US3302383

Folder: SAE USA-US087-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:00:55

**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.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:04:02
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:35:35
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:20:06
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 18:27:16