

US3112223 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:11:25

All time stamps listed in this document are displayed in GMT

US3112223

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 19:17:48

Generated On: 09 Jun 2021 15:11:25

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[Participant ID](#)

US3112223

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

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US3112223

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3112223

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	CARDIAC STENT
Start date (dd MMM yyyy)	14 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	14 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	TRIGIMINY CARDIAC ARRYTHIMIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	14 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN APR 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 JUL 2015
Stop date completely unknown	False
Start Month and Year (derived)	APR 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUL 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	03 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 JUL 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUL 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	HERPES SIMPLEX VIRUS, RECURRENT
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3112223

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Condition	GOUT
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)	_____

US3112223

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:05 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 08:05
Height ( <i>xxx.x</i> )	70.5 in
Weight ( <i>xxx.x</i> )	195 lb
BMI ( <i>xxx.x</i> )	27.64180 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:18:00

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<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>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 185997

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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)	13 AUG 2020
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 08:05
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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)	13 AUG 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:09
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 09:38

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	08:39 (24 HR)
Collection date and time (derived)	13 AUG 2020 08:39

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:32	13 AUG 2020 08:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

13 AUG 2020 10:11

PC Open Date & Time

13 AUG 2020 09:58

PC Close Date & Time

13 AUG 2020 12:28

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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 97.1 °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	14 AUG 2020 04:19
PC Open Date & Time	13 AUG 2020 13:23
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	15 AUG 2020 14:10
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 13:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 07:39

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 10:12

PC Open Date & Time

13 AUG 2020 09:58

PC Close Date & Time

13 AUG 2020 12:28

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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

14 AUG 2020 04:20

PC Open Date & Time

13 AUG 2020 13:23

PC Close Date & Time

14 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**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

15 AUG 2020 14:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**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

16 AUG 2020 13:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**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

19 AUG 2020 07:39

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 10:13
PC Open Date & Time	13 AUG 2020 09:58
PC Close Date & Time	13 AUG 2020 12:28

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 04:21
PC Open Date & Time	13 AUG 2020 13:23
PC Close Date & Time	14 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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 ☐

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EAB) (1725)

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2193

EAB) (1725)

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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 ☒

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EAB) (1725)

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 13:27
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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 ☒

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 07:40
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112223

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112223

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:51

Generated On: 09 Jun 2021 15:11:25

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

UNABLE TO REACH PATIENT  
DUE TO SITE SCHEDULING  
ERROR

If Contact Not Made, please provide Comments

US3112223

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:51

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3112223

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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)	23 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 11:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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)	23 SEP 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:05
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3112223

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

23 SEP 2020

---

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

---

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 12:34 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 12:34

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

US3112223

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	12:30 (24 HR)
Collection date and time (derived)	23 SEP 2020 12:30

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:06	23 SEP 2020 12:06
Nasopharyngeal Swab 2	No		

US3112223

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:54

PC Close Date & Time

23 SEP 2020 15:24

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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 97.9 °F

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

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

PC Time Stamp	23 SEP 2020 20:56
PC Open Date & Time	23 SEP 2020 16:19
PC Close Date & Time	24 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 21:33

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 06:43

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

23 SEP 2020 12:54

PC Close Date & Time

23 SEP 2020 15:24

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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

23 SEP 2020 20:56

PC Open Date & Time

23 SEP 2020 16:19

PC Close Date & Time

24 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 21:34

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**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

30 SEP 2020 06:44

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:54

PC Close Date & Time

23 SEP 2020 15:24

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 20:57
PC Open Date & Time	23 SEP 2020 16:19
PC Close Date & Time	24 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**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 ☒

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 21:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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 ☐

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**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 ☐

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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 ☐

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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 ☒

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EAB) (1725)

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 06:44
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3112223

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112223

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy) \_\_\_\_\_

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

Comments

If Contact Not Made, please provide Comments \_\_\_\_\_

US3112223

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy) \_\_\_\_\_

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

Comments

If Contact Not Made, please provide Comments \_\_\_\_\_

US3112223

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:11 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 08:11
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	182 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112223

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

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.*

US3112223

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	08:20 (24 HR)
Collection date and time (derived)	28 OCT 2020 08:20

US3112223

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:01

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**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

24 OCT 2020 12:40:18

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**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

21 NOV 2020 07:43:22

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**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

05 DEC 2020 06:12:52

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**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

20 DEC 2020 16:45:39

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

**US3112223**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 15:11:25**

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

US3112223

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112223

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:18:00

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112223

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:51

Generated On: 09 Jun 2021 15:11:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112223

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:51

Generated On: 09 Jun 2021 15:11:25

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Date of Contact	03 SEP 2020
Time of Contact	17:45
Date and Time of Contact (derived)	03 SEP 2020 17:45
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	99.3 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)

149 of 2193

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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 ☐

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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 ☐

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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 ☐

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	101.5 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)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 JAN 2021	
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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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)

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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"/>

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Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Date of Visit	3 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	3 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)	0

**US3112223**

**Folder: Covid-19 Assessment 03 Sep 2020**

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

**Generated On: 09 Jun 2021 15:11:25**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	05 SEP 2020
Day 5	Yes	7 SEP 2020
Day 7	Yes	09 SEP 2020
Day 9	Yes	11 SEP 2020
Day 14	Yes	16 SEP 2020
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3112223

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	19:35 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 19:35
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 SEP 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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.*

US3112223

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 19:17:49

Generated On: 09 Jun 2021 15:11:25

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:16:37

Generated On: 09 Jun 2021 15:11:25

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

AEID	USA-US062-2020-MRNA-1273-P30 1000001
Adverse event	STREP-PHARYNGITIS
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)	01 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)	14 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)	02 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	03 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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 checked="" type="radio"/> Investigational Product Withdrawn <input 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	

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

---

REPORTS FEVER, CHILLS, SORE  
THROAT AND MALAISE, ON  
02SEP2020. WENT TO ER AND  
ADMITTED OVERNIGHT. HAD 3  
NEG COVID TESTS IN ER.  
AMOXICILLIAN PRESCRIBED  
ON DISCHARGE. SYMPTOMS  
HAVE SINCE RECOVERED.

---

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

---

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

---

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

Yes ☒

No ☐

---

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

---

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication CRESTOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication PLAVIX

Prophylaxis Yes ☐  
No ☒

Indication CAD S/P STENT

Dose per administration 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

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Name of Medication ALLOPURINOL

Prophylaxis Yes ☐  
No ☒

Indication GOUT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication HEALTH SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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)		01 JAN 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication BERBERINE

Prophylaxis Yes ☐  
No ☒

Indication HEALTH SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication DIOVAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 320

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication STREPP-PHARYNGITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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)		02 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) 14 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication FEVER REDUCTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	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)		02 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) 02 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA VIRUS  
PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 19:17:49

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

Name of Medication VALTREX

Prophylaxis Yes ☐  
No ☒

Indication HERPES SIMPLEX VIRUS

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 19:17:49

Generated On: 09 Jun 2021 15:11:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 19:17:49

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---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

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Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
02 SEP 2020	IN-PATIENT COVID PCR	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

Date of study discontinuation/completion (dd MMM yyyy) 14 JAN 2021

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 type="checkbox"/>
Other	<input checked="" type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify REQUEST TO UNBLIND/ EUA COVID-19 VACCINE

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"/>

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/SEP/2020 14:58
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

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/SEP/2020 21:39
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

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 17:11
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

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 19:17:50

Generated On: 09 Jun 2021 15:11:25

SAEID	USA-US062-2020-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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/OCT/2020 19:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3112223 (Prod: Medical Center For Clinical Research - M3 Wake Research)

**US3112223**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:11:25**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'US3112223'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 15:40:09

US3112223

Form: Participant Creation

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 16:49:30

US3112223

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 15:40:10

US3112223

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	13 Aug 2020 16:49:30

**US3112223**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'SCRN'	System	13 Aug 2020 16:49:30

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 15:40:11

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:20:51
Query 'Per CDM: Please complete this form.' answered with 'This is completed.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 16:06:25
User entered '65'	(b) (4), (b) (6)	19 Aug 2020 16:06:14
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 15:45:41

**US3112223**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:25**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'YEARS'	System	19 Aug 2020 16:06:14

**US3112223**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:25**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '65'	System	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:14

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Aug 2020'	System	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2020'	System	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:49:47

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 15:40:10

US3112223

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:11:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 02:27:21
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 20:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 20:29:45
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:07:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:12:19

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 20:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:32:41
Data point term sent to Coder	System	05 Sep 2020 20:31:16
User entered 'Hypercholesterolemia'	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'UN UNK 2005'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:28

**US3112223**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:28

**US3112223**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2005'	System	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2005'	System	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	05 Sep 2020 20:30:28

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:32:41
Data point term sent to Coder	System	05 Sep 2020 20:31:17
User entered 'Hypertension'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'UN UNK 1980'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

**US3112223**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 1980'	System	05 Sep 2020 20:30:49

**US3112223**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1980'	System	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	05 Sep 2020 20:30:49

**US3112223**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	05 Sep 2020 20:30:49

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:33:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:33:41
Data point term sent to Coder	System	05 Sep 2020 20:32:17
User entered 'Cardiac Stent'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '14 Oct 2019'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

**US3112223**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '14 Oct 2019'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Oct 2019'	System	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2019'	System	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Oct 2019'	System	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2019'	System	05 Sep 2020 20:31:47

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Extrasystoles, LLT: Trigeminy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	01 Nov 2020 17:42:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Nov 2020 17:42:51
User closed query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:38:56
Data point term sent to Coder	System	28 Oct 2020 16:16:28
Query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated and reconciled' (Site from DM).	Natalie Moy (b) (4)	28 Oct 2020 16:15:50
Coding entries removed.	Natalie Moy (b) (4)	28 Oct 2020 16:15:44
User entered 'trigeminy CARDIAC ARRYTHMIA' reason for change: New Information	Natalie Moy (b) (4)	28 Oct 2020 16:15:44
User opened query 'Per DM CLR: Please specify the type of Arrhythmia (eg. bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:02:10
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	06 Sep 2020 04:35:41

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	06 Sep 2020 04:35:41 05 Sep 2020 20:33:18
User entered 'Cardiac Arrythimia'	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'UN UNK 2017'	Karen Mylerberg (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '14 Oct 2019'	Karen Mylerberg (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2017'	System	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2017'	System	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Oct 2019'	System	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2019'	System	05 Sep 2020 20:32:32

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Sep 2020 20:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:34:42
Data point term sent to Coder	System	05 Sep 2020 20:34:19
User entered 'Prostate cancer'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'UN Apr 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

**US3112223**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '03 Jul 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Apr 2015'	System	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2015'	System	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jul 2015'	System	05 Sep 2020 20:34:03

**US3112223**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2015'	System	05 Sep 2020 20:34:03

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Sep 2020 20:35:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:35:42
Data point term sent to Coder	System	05 Sep 2020 20:35:22
User entered 'Prostatectomy'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '03 Jul 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '03 Jul 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jul 2015'	System	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2015'	System	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jul 2015'	System	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2015'	System	05 Sep 2020 20:34:52

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:54:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:54:55
Data point term sent to Coder	System	10 Sep 2020 15:53:05
User entered 'Coronary artery disease'	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Karen Mylerberg (b) (4)	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2019'	System	10 Sep 2020 15:53:02

**US3112223**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2019'	System	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	10 Sep 2020 15:53:02

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Oct 2020 18:42:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:42:17
Data point term sent to Coder	System	28 Oct 2020 16:20:34
User entered 'obstructive sleep apnea'	Natalie Moy (b) (4)	28 Oct 2020 16:19:50
	(b) (4)	

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'un UNK 2010'	Natalie Moy (b) (4)	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Natalie Moy (b) (4)	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Natalie Moy (b) (4)	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2010'	System	28 Oct 2020 16:19:50

**US3112223**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2010'	System	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:19:50

**US3112223**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:19:50

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Oct 2020 16:43:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:43:54
Data point term sent to Coder	System	28 Oct 2020 16:20:35
User entered 'herpes simplex virus, recurrent'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'un UNK 2010'	Natalie Moy (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) Natalie Moy (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Natalie Moy (b) (4)	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2010'	System	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2010'	System	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:20:24

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:42:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:42:31
Data point term sent to Coder	System	28 Oct 2020 16:23:39
User entered 'gout'	Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'un UNK 2015'	Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) Natalie Moy (b) (4)	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'Jan 2015'	System	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2015'	System	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:23:06

**US3112223**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:23:06

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:05'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 08:05'	System	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '70.5' in	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10
DataPoint set to visible.	System	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '195' lb	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10
DataPoint set to visible.	System	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: User entered '27.64180'	System	16 Sep 2020 23:55:20
User entered '27.6'	System	19 Aug 2020 16:09:10
DataPoint set to visible.	System	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'kg/m2'	System	19 Aug 2020 16:09:10
DataPoint set to visible.	System	13 Aug 2020 16:49:54

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 03:41:53
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	04 Sep 2020 00:52:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	04 Sep 2020 00:52:45
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)	21 Aug 2020 15:44:22
User entered '97.8' F	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	04 Sep 2020 00:52:45
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 00:52:45
User entered '93'	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 00:52:45
User entered '15'	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 00:52:45
User entered '115'	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 00:52:45
User entered '58'	(b) (4), (b) (6)	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:09:10

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:49

US3112223

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:49

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:07:24

US3112223

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:12:27

US3112223

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:12:27

US3112223

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:12:27

US3112223

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'VISIT1'	System	19 Aug 2020 16:12:27

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:04:23

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:11:00
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:11:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:04:23
User entered '185997' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:04:23

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:04:23

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:46

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:46

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:46

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:46

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:06:46

US3112223

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:25

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 12:55:19
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 16:49:57
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 16:49:51
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:52:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:30

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:05'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 08:05'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '93'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '15'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '115'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:09:07
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 20:18:58
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:55:20
User entered '58'	(b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:10:56
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 16:10:43
User entered '10:09'	(b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 10:09'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '66'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '118'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '62'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	19 Aug 2020 16:10:43

US3112223

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:41

US3112223

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:41

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '09:38'	(b) (4) Matthew Musikanth	13 Aug 2020 16:50:25
	(b) (4)	

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 09:38'	System	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'ONCE'	System	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 16:50:25

US3112223

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:28

US3112223

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:28

US3112223

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:39'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:28

US3112223

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 08:39'	System	19 Aug 2020 16:11:28

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:32'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '13 Aug 2020 08:32'	System	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	19 Aug 2020 16:11:12

US3112223

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:12:34

US3112223

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	19 Aug 2020 16:12:34

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:11:17', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '3e594c53-af42-4f98-8321-c677922345fc' User entered 'Yes (Y)'	System	13 Aug 2020 17:11:51
	System	13 Aug 2020 17:11:51

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:11:25', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '3e594c53-af42-4f98-8321-c677922345fc' User entered '97.1'	System	13 Aug 2020 17:11:51
	System	13 Aug 2020 17:11:51

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:11:44', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '3e594c53-af42-4f98-8321-c677922345fc'	System	13 Aug 2020 17:11:51
User entered 'No (N)'	System	13 Aug 2020 17:11:51

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:11:50', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '3e594c53-af42-4f98-8321-c677922345fc' User entered '13 Aug 2020 10:11'	System	13 Aug 2020 17:11:51
	System	13 Aug 2020 17:11:51

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 09:58'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 12:28'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:19', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b7be3106-d90a-49a4-8153-571eda967468' User entered 'Yes (Y)'	System	14 Aug 2020 11:19:45
	System	14 Aug 2020 11:19:45

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:31', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b7be3106-d90a-49a4-8153-571eda967468' User entered '97.1'	System	14 Aug 2020 11:19:45
	System	14 Aug 2020 11:19:45

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:36', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b7be3106-d90a-49a4-8153-571eda967468'	System	14 Aug 2020 11:19:45
User entered 'No (N)'	System	14 Aug 2020 11:19:45

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:44', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b7be3106-d90a-49a4-8153-571eda967468' User entered '14 Aug 2020 04:19'	System	14 Aug 2020 11:19:45
	System	14 Aug 2020 11:19:45

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 13:23'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 2'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 3'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:28', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered 'Yes (Y)'	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:34', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered '97.2'	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:38', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered 'Yes (Y)'	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'mistake, pt contacted and no meds reported taken ' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 11:58:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:43', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered '1'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:17:02
	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:43', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered '0'	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:47', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5d1cf510-f1e1-4445-b94d-56ffb0b0be4b' User entered '15 Aug 2020 14:10'	System	15 Aug 2020 21:10:49
	System	15 Aug 2020 21:10:49

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 4'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:16', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '70ccf1d8-c5ae-4cd5-a89f-2aa86accd8f3' User entered 'Yes (Y)'	System	16 Aug 2020 20:26:33
	System	16 Aug 2020 20:26:33

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:22', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '70ccf1d8-c5ae-4cd5-a89f-2aa86accd8f3' User entered '97.0'	System	16 Aug 2020 20:26:33
	System	16 Aug 2020 20:26:33

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:26', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '70ccf1d8-c5ae-4cd5-a89f-2aa86accd8f3'	System	16 Aug 2020 20:26:33
User entered 'No (N)'	System	16 Aug 2020 20:26:33

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:30', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '70ccf1d8-c5ae-4cd5-a89f-2aa86accd8f3' User entered '16 Aug 2020 13:26'	System	16 Aug 2020 20:26:33
	System	16 Aug 2020 20:26:33

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 5'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 6'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:10', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '292b8a1f-5b1c-4c98-afeb-3b2d8d0c2a42' User entered 'Yes (Y)'	System	19 Aug 2020 14:39:29
	System	19 Aug 2020 14:39:29

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:17', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '292b8a1f-5b1c-4c98-afeb-3b2d8d0c2a42' User entered '97.3'	System	19 Aug 2020 14:39:29
	System	19 Aug 2020 14:39:29

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:22', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '292b8a1f-5b1c-4c98-afeb-3b2d8d0c2a42'	System	19 Aug 2020 14:39:29
User entered 'No (N)'	System	19 Aug 2020 14:39:29

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:27', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '292b8a1f-5b1c-4c98-afeb-3b2d8d0c2a42'	System	19 Aug 2020 14:39:29
User entered '19 Aug 2020 07:39'	System	19 Aug 2020 14:39:29

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 7'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:11:57', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '227decc8-6e2b-4479-8f47-d5599148a0b5' User entered 'None (1)'	System	13 Aug 2020 17:12:46
	System	13 Aug 2020 17:12:46

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:01', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '227decc8-6e2b-4479-8f47-d5599148a0b5' User entered 'No (N)'	System	13 Aug 2020 17:12:46
	System	13 Aug 2020 17:12:46

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:05', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '227decc8-6e2b-4479-8f47-d5599148a0b5' User entered 'No (N)'	System	13 Aug 2020 17:12:46
	System	13 Aug 2020 17:12:46

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:33', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '227decc8-6e2b-4479-8f47-d5599148a0b5' User entered 'None (1)'	System	13 Aug 2020 17:12:46
	System	13 Aug 2020 17:12:46

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:40', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '227decc8-6e2b-4479-8f47-d5599148a0b5' User entered '13 Aug 2020 10:12'	System	13 Aug 2020 17:12:46
	System	13 Aug 2020 17:12:46

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 09:58'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 12:28'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:50', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd7186c85-994d-46ea-81c5-e105244c9797'	System	14 Aug 2020 11:20:07
User entered 'None (1)'	System	14 Aug 2020 11:20:07

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:54', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd7186c85-994d-46ea-81c5-e105244c9797'	System	14 Aug 2020 11:20:07
User entered 'No (N)'	System	14 Aug 2020 11:20:07

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:19:57', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd7186c85-994d-46ea-81c5-e105244c9797' User entered 'No (N)'	System	14 Aug 2020 11:20:07
	System	14 Aug 2020 11:20:07

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:01', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd7186c85-994d-46ea-81c5-e105244c9797'	System	14 Aug 2020 11:20:07
User entered 'None (1)'	System	14 Aug 2020 11:20:07

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:05', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd7186c85-994d-46ea-81c5-e105244c9797'	System	14 Aug 2020 11:20:07
User entered '14 Aug 2020 04:20'	System	14 Aug 2020 11:20:07

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 13:23'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 2'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 3'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:10:51', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '4fdd9272-1cb3-4fa3-921a-e326db58c76e' User entered 'None (1)'	System	15 Aug 2020 21:11:35
	System	15 Aug 2020 21:11:35

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:24', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '4fdd9272-1cb3-4fa3-921a-e326db58c76e' User entered 'No (N)'	System	15 Aug 2020 21:11:35
	System	15 Aug 2020 21:11:35

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:27', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '4fdd9272-1cb3-4fa3-921a-e326db58c76e' User entered 'No (N)'	System	15 Aug 2020 21:11:35
	System	15 Aug 2020 21:11:35

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:30', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '4fdd9272-1cb3-4fa3-921a-e326db58c76e' User entered 'None (1)'	System	15 Aug 2020 21:11:35
	System	15 Aug 2020 21:11:35

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:33', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '4fdd9272-1cb3-4fa3-921a-e326db58c76e' User entered '15 Aug 2020 14:11'	System	15 Aug 2020 21:11:35
	System	15 Aug 2020 21:11:35

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 4'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:34', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '9de2f39e-a368-462d-a4bb-6f1025772e6e' User entered 'None (1)'	System	16 Aug 2020 20:26:49
	System	16 Aug 2020 20:26:49

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:37', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '9de2f39e-a368-462d-a4bb-6f1025772e6e' User entered 'No (N)'	System	16 Aug 2020 20:26:49
	System	16 Aug 2020 20:26:49

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:39', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '9de2f39e-a368-462d-a4bb-6f1025772e6e' User entered 'No (N)'	System	16 Aug 2020 20:26:49
	System	16 Aug 2020 20:26:49

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:42', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '9de2f39e-a368-462d-a4bb-6f1025772e6e' User entered 'None (1)'	System	16 Aug 2020 20:26:49
	System	16 Aug 2020 20:26:49

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:46', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '9de2f39e-a368-462d-a4bb-6f1025772e6e' User entered '16 Aug 2020 13:26'	System	16 Aug 2020 20:26:49
	System	16 Aug 2020 20:26:49

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 5'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 6'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:32', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '77284dcf-a4f6-4616-b3b0-d5994fa132b9' User entered 'None (1)'	System	19 Aug 2020 14:39:43
	System	19 Aug 2020 14:39:43

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:34', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '77284dcf-a4f6-4616-b3b0-d5994fa132b9' User entered 'No (N)'	System	19 Aug 2020 14:39:43
	System	19 Aug 2020 14:39:43

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:36', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '77284dcf-a4f6-4616-b3b0-d5994fa132b9'	System	19 Aug 2020 14:39:43
User entered 'No (N)'	System	19 Aug 2020 14:39:43

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:39', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '77284dcf-a4f6-4616-b3b0-d5994fa132b9' User entered 'None (1)'	System	19 Aug 2020 14:39:43
	System	19 Aug 2020 14:39:43

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:42', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '77284dcf-a4f6-4616-b3b0-d5994fa132b9' User entered '19 Aug 2020 07:39'	System	19 Aug 2020 14:39:43
	System	19 Aug 2020 14:39:43

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 7'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:49', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:52', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:54', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:12:58', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:13:02', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:13:04', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'None (0)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:13:10', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered 'No (N)'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-13T10:13:13', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'edee4e51-6ce6-4617-ad6d-c3740e9d43a7' User entered '13 Aug 2020 10:13'	System	13 Aug 2020 17:13:18
	System	13 Aug 2020 17:13:18

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 09:58'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 12:28'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:11', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'None (0)'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:21', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'Significant; prevents daily activity (3)'	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:21:00', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'None (0)'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:29', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'None (0)'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:36', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f'	System	14 Aug 2020 11:21:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:39', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'None (0)'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:20:43', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered 'No (N)'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-14T04:21:11', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '41cfad32-dba3-4cf6-aa57-32e34363ac6f' User entered '14 Aug 2020 04:21'	System	14 Aug 2020 11:21:13
	System	14 Aug 2020 11:21:13

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '13 Aug 2020 13:23'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 2'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 3'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:37', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:40', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:43', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:45', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:48', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:50', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'None (0)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:53', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered 'No (N)'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-15T14:11:57', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '0ca6a902-3431-4b73-aaa0-38dff20947ee' User entered '15 Aug 2020 14:11'	System	15 Aug 2020 21:12:00
	System	15 Aug 2020 21:12:00

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 4'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:51', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered 'None (0)'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:53', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered 'None (0)'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:55', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245' User entered 'None (0)'	System	16 Aug 2020 20:27:11
	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:26:58', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245' User entered 'None (0)'	System	16 Aug 2020 20:27:11
	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:27:00', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered 'None (0)'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:27:02', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered 'None (0)'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:27:05', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered 'No (N)'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-16T13:27:07', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'b99e4500-cdf0-449e-a623-7dc26dd9c245'	System	16 Aug 2020 20:27:11
User entered '16 Aug 2020 13:27'	System	16 Aug 2020 20:27:11

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 5'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 6'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:46', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:47', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:49', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:51', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:53', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

**US3112223**

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

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

**Generated On: 09 Jun 2021 15:11:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:56', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'None (0)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:39:59', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered 'No (N)'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-08-19T07:40:01', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '411761f1-8669-4411-a6a8-2bb67005262c' User entered '19 Aug 2020 07:40'	System	19 Aug 2020 14:40:03
	System	19 Aug 2020 14:40:03

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 7'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:50:25

US3112223

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:15:52

US3112223

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:15:52

US3112223

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:15:52

US3112223

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:15:52

US3112223

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:15:58

US3112223

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	20 Aug 2020 15:15:58

US3112223

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 23:11:14

US3112223

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	20 Oct 2020 23:11:14
	(b) (4)	

US3112223

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	20 Oct 2020 23:11:14
	(b) (4)	

US3112223

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Unable to reach patient due to site scheduling error'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 23:11:14

US3112223

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:03

US3112223

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Sep 2020 19:42:03

US3112223

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 23:10:51

US3112223

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 23:10:51

US3112223

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	20 Oct 2020 23:10:51

US3112223

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Matthew Musikanth	20 Oct 2020 23:10:51
	(b) (4)	

US3112223

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:09

US3112223

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Sep 2020 19:42:09

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted however sample dated 23sep2020 is not reported under Visit 3 Day 57visit in EDC. Please confirm date for VISIT 3 day 57 to be updated in the PPD central for the Antibody-mediated Immunogenicity.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:13:27
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted however sample dated 23sep2020 is not reported under Visit 3 Day 57visit in EDC. Please confirm date for VISIT 3 day 57 to be updated in the PPD central for the Antibody-mediated Immunogenicity.' answered with 'sample dated 23sept2020 was listed for visit 2, but updated visit 3 day 57 additionally ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:09:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted however sample dated 23sep2020 is not reported under Visit 3 Day 57visit in EDC. Please confirm date for VISIT 3 day 57 to be updated in the PPD central for the Antibody-mediated Immunogenicity.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:39:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:35:52
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'subject was seen the 23sep2020' (Site from DM).	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 17:06:11

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 06:11:57
	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 19:42:18

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:33:19
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'visit date is confirmed as entered correctly. Visit out of window due to illness visits.' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	24 Sep 2020 23:59:44
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 19:42:18
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:42:18

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:18

US3112223

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'VISIT2'	System	23 Sep 2020 19:42:18

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Pre-Dose (PREDOSE)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '23 Sep 2020'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '11:50'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '23 Sep 2020 11:50'	System	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '98.2' F	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '85'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '16'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '153'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '92'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:25
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	25 Sep 2020 00:00:25

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Post-Dose (POSTDOSE)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '23 Sep 2020'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '13:05'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '23 Sep 2020 13:05'	System	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '98.6' F	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '74'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '16'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '136'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '74'	Nicolle Mendez (b) (4)	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	25 Sep 2020 00:00:56

US3112223

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 16:39:05
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
	System	25 Sep 2020 00:01:21
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	25 Sep 2020 00:01:09
User entered 'No (N)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:01:09
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:39:18
User entered '23 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 16:39:18
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 16:39:05
User entered '22 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 16:39:05
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 00:01:21
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4)	25 Sep 2020 00:01:21
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 00:01:09
User entered '24 Sep 2020'	Nicolle Mendez (b) (4)	25 Sep 2020 00:01:09

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '12:34'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '23 Sep 2020 12:34'	System	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'ONCE'	System	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 19:42:34

US3112223

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:01:49

US3112223

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '23 Sep 2020'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:01:49
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '12:30'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:01:49

US3112223

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '23 Sep 2020 12:30'	System	25 Sep 2020 00:01:49

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '23 Sep 2020'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '12:06'	(b) (4) Nicolle Mendez (b) (4) (b) (4)	25 Sep 2020 00:02:03

**US3112223**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '23 Sep 2020 12:06'	System	25 Sep 2020 00:02:03

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Nicolle Mendez (b) (4)	25 Sep 2020 00:02:03
	(b) (4)	

US3112223

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	25 Sep 2020 00:02:03

US3112223

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:42

US3112223

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Sep 2020 19:42:42

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 12:54'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 15:24'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:14', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '71a4e376-81cc-4db3-b879-c4f99864c160' User entered 'Yes (Y)'	System	24 Sep 2020 03:56:32
	System	24 Sep 2020 03:56:32

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:21', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '71a4e376-81cc-4db3-b879-c4f99864c160' User entered '97.9'	System	24 Sep 2020 03:56:32
	System	24 Sep 2020 03:56:32

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:25', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '71a4e376-81cc-4db3-b879-c4f99864c160'	System	24 Sep 2020 03:56:32
User entered 'No (N)'	System	24 Sep 2020 03:56:32

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:30', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '71a4e376-81cc-4db3-b879-c4f99864c160' User entered '23 Sep 2020 20:56'	System	24 Sep 2020 03:56:32
	System	24 Sep 2020 03:56:32

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 16:19'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 2'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:30', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '05447871-53f5-4936-94a1-a5c03bebcda8' User entered 'Yes (Y)'	System	25 Sep 2020 04:33:50
	System	25 Sep 2020 04:33:50

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:38', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '05447871-53f5-4936-94a1-a5c03bebcda8' User entered '97.2'	System	25 Sep 2020 04:33:50
	System	25 Sep 2020 04:33:50

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:42', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '05447871-53f5-4936-94a1-a5c03bebcda8'	System	25 Sep 2020 04:33:50
User entered 'No (N)'	System	25 Sep 2020 04:33:50

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:48', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '05447871-53f5-4936-94a1-a5c03bebcda8' User entered '24 Sep 2020 21:33'	System	25 Sep 2020 04:33:50
	System	25 Sep 2020 04:33:50

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 3'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 4'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 5'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 6'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 7'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:43:36', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '763c003c-9fd0-4973-8208-312edd947b6b' User entered 'Yes (Y)'	System	30 Sep 2020 13:43:57
	System	30 Sep 2020 13:43:57

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:43:43', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '763c003c-9fd0-4973-8208-312edd947b6b' User entered '97.4'	System	30 Sep 2020 13:43:57
	System	30 Sep 2020 13:43:57

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:43:47', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '763c003c-9fd0-4973-8208-312edd947b6b' User entered 'No (N)'	System	30 Sep 2020 13:43:57
	System	30 Sep 2020 13:43:57

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:43:52', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '763c003c-9fd0-4973-8208-312edd947b6b' User entered '30 Sep 2020 06:43'	System	30 Sep 2020 13:43:57
	System	30 Sep 2020 13:43:57

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 12:54'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 15:24'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:36', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd1e7e3fc-d565-481f-8797-987b5b07b4e7' User entered 'None (1)'	System	24 Sep 2020 03:56:55
	System	24 Sep 2020 03:56:55

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:39', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd1e7e3fc-d565-481f-8797-987b5b07b4e7' User entered 'No (N)'	System	24 Sep 2020 03:56:55
	System	24 Sep 2020 03:56:55

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:42', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd1e7e3fc-d565-481f-8797-987b5b07b4e7' User entered 'No (N)'	System	24 Sep 2020 03:56:55
	System	24 Sep 2020 03:56:55

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:46', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd1e7e3fc-d565-481f-8797-987b5b07b4e7'	System	24 Sep 2020 03:56:55
User entered 'None (1)'	System	24 Sep 2020 03:56:55

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:56:50', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'd1e7e3fc-d565-481f-8797-987b5b07b4e7' User entered '23 Sep 2020 20:56'	System	24 Sep 2020 03:56:55
	System	24 Sep 2020 03:56:55

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 16:19'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 2'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:54', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '402a9320-9764-4ced-9295-a0e436332aca' User entered 'None (1)'	System	25 Sep 2020 04:34:11
	System	25 Sep 2020 04:34:11

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:33:57', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '402a9320-9764-4ced-9295-a0e436332aca' User entered 'No (N)'	System	25 Sep 2020 04:34:11
	System	25 Sep 2020 04:34:11

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:00', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '402a9320-9764-4ced-9295-a0e436332aca' User entered 'No (N)'	System	25 Sep 2020 04:34:11
	System	25 Sep 2020 04:34:11

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:06', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '402a9320-9764-4ced-9295-a0e436332aca' User entered 'None (1)'	System	25 Sep 2020 04:34:11
	System	25 Sep 2020 04:34:11

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:09', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '402a9320-9764-4ced-9295-a0e436332aca' User entered '24 Sep 2020 21:34'	System	25 Sep 2020 04:34:11
	System	25 Sep 2020 04:34:11

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 3'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 4'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 5'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 6'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 7'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:43:59', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'ef9945ab-6079-4abf-9286-bb49e9c11a93'	System	30 Sep 2020 13:44:17
User entered 'None (1)'	System	30 Sep 2020 13:44:17

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:02', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'ef9945ab-6079-4abf-9286-bb49e9c11a93'	System	30 Sep 2020 13:44:17
User entered 'No (N)'	System	30 Sep 2020 13:44:17

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:05', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'ef9945ab-6079-4abf-9286-bb49e9c11a93' User entered 'No (N)'	System	30 Sep 2020 13:44:17
	System	30 Sep 2020 13:44:17

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:08', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'ef9945ab-6079-4abf-9286-bb49e9c11a93' User entered 'None (1)'	System	30 Sep 2020 13:44:17
	System	30 Sep 2020 13:44:17

**US3112223**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:11:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:12', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'ef9945ab-6079-4abf-9286-bb49e9c11a93' User entered '30 Sep 2020 06:44'	System	30 Sep 2020 13:44:17
	System	30 Sep 2020 13:44:17

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 12:54'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 15:24'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:10', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'None (0)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:49', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'No interference with activity (1)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:13', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'None (0)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:16', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'None (0)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:25', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da'	System	24 Sep 2020 03:57:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:28', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'None (0)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:32', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered 'No (N)'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-23T20:57:52', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '8179a3f3-54dc-431d-ac13-3a763c14b6da' User entered '23 Sep 2020 20:57'	System	24 Sep 2020 03:57:54
	System	24 Sep 2020 03:57:54

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '23 Sep 2020 16:19'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 2'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:14', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:16', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:18', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:20', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:23', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:25', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'None (0)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:29', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered 'No (N)'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-24T21:34:31', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '5a923a99-579c-42bc-a729-81fd6bdbbeaa6' User entered '24 Sep 2020 21:34'	System	25 Sep 2020 04:34:35
	System	25 Sep 2020 04:34:35

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 3'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 4'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 5'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 6'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	23 Sep 2020 19:42:34
User entered 'Day 7'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:16', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:18', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:20', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:22', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:24', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:26', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'None (0)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:28', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered 'No (N)'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

**US3112223**

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

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

**Generated On: 09 Jun 2021 15:11:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-09-30T06:44:31', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2b1c5375-27b3-4944-85bf-e3b5fd57fc4b' User entered '30 Sep 2020 06:44'	System	30 Sep 2020 13:44:33
	System	30 Sep 2020 13:44:33

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:42:34

US3112223

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:42:34

US3112223

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Natalie Moy (b) (4)	23 Nov 2020 18:10:31

US3112223

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:10:31

US3112223

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:10:31

US3112223

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:10:31

US3112223

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Natalie Moy (b) (4)	23 Nov 2020 18:10:35

US3112223

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Nov 2020 18:10:35

US3112223

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Natalie Moy (b) (4)	23 Nov 2020 18:10:43

US3112223

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Natalie Moy (b) (4)	23 Nov 2020 18:10:43

US3112223

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:10:43

US3112223

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:10:43

US3112223

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Natalie Moy (b) (4)	23 Nov 2020 18:10:50

US3112223

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Nov 2020 18:10:50

US3112223

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:01

US3112223

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:01

US3112223

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:01

US3112223

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:01

US3112223

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:13

US3112223

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Nov 2020 18:11:13

US3112223

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3112223

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '28 Oct 2020'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:11:27

US3112223

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	23 Nov 2020 18:11:27

US3112223

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'VISIT3'	System	23 Nov 2020 18:11:27

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '28 Oct 2020'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:11'	(b) (4) Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '28 Oct 2020 08:11'	System	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '98.3' F	Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Oral (Oral)'	(b) (4) Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '62'	Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '14'	(b) (4) Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '182'	Natalie Moy (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '95'	(b) (4) Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	23 Nov 2020 18:12:17

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Natalie Moy (b) (4)	23 Nov 2020 18:12:30

US3112223

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Natalie Moy (b) (4)	23 Nov 2020 18:12:30

US3112223

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Natalie Moy (b) (4)	23 Nov 2020 18:12:46

US3112223

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 08:33:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' answered with 'pt was seen the 28th. They didn't have a blooddraw the 23Oct/2020' (Site from DM).	Natalie Moy (b) (4) (b) (4)	24 Nov 2020 16:51:15
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however 23OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:42:40
User entered '28 Oct 2020'	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 18:12:46

US3112223

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered '08:20'	Natalie Moy (b) (4)	23 Nov 2020 18:12:46

US3112223

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '28 Oct 2020 08:20'	System	23 Nov 2020 18:12:46

US3112223

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Natalie Moy (b) (4)	23 Nov 2020 18:12:50

US3112223

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	23 Nov 2020 18:12:50

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 64'	System	13 Aug 2020 16:50:25

US3112223

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 71'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-10-24T12:40:06', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2292eef7-1c35-455b-9e32-cac1a3ad4227'	System	24 Oct 2020 19:40:22
User entered 'No (N)'	System	24 Oct 2020 19:40:22

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

Have you been exposed to someone with 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)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-10-24T12:40:11', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2292eef7-1c35-455b-9e32-cac1a3ad4227'	System	24 Oct 2020 19:40:22
User entered 'No (N)'	System	24 Oct 2020 19:40:22

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-10-24T12:40:18', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '2292eef7-1c35-455b-9e32-cac1a3ad4227' User entered '24 Oct 2020 12:40:18'	System	24 Oct 2020 19:40:22
	System	24 Oct 2020 19:40:22

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 16:50:25

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:44
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 78'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

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[Please 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)
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
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**Folder: Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 16:50:25

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 92'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

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**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 16:50:25

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered 'Day 99'	System	13 Aug 2020 16:50:25

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Please 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)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 16:50:25

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:06:07
Data entry locked.	System	13 Aug 2020 16:50:25
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 16:50:25

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-11-21T07:43:09', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '30e0ee08-d081-4695-b351-fd39fcd1312b' User entered 'No (N)'	System	21 Nov 2020 15:43:24
	System	21 Nov 2020 15:43:24

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-11-21T07:43:15', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '30e0ee08-d081-4695-b351-fd39fcd1312b' User entered 'No (N)'	System	21 Nov 2020 15:43:24
	System	21 Nov 2020 15:43:24

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-11-21T07:43:22', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '30e0ee08-d081-4695-b351-fd39fcd1312b' User entered '21 Nov 2020 07:43:22'	System	21 Nov 2020 15:43:24
	System	21 Nov 2020 15:43:24

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-05T06:12:41', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'deebb4b6-44fc-48ae-881f-fdb2eeeb856a' User entered 'No (N)'	System	05 Dec 2020 14:12:56
	System	05 Dec 2020 14:12:56

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-05T06:12:48', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'deebb4b6-44fc-48ae-881f-fdb2eeeb856a' User entered 'No (N)'	System	05 Dec 2020 14:12:56
	System	05 Dec 2020 14:12:56

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-05T06:12:52', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: 'deebb4b6-44fc-48ae-881f-fdb2eeeb856a' User entered '05 Dec 2020 06:12:52'	System	05 Dec 2020 14:12:56
	System	05 Dec 2020 14:12:56

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-20T16:45:29', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '57b34aff-6148-4f6f-a961-489f28848515' User entered 'No (N)'	System	21 Dec 2020 00:45:41
	System	21 Dec 2020 00:45:41

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-20T16:45:34', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '57b34aff-6148-4f6f-a961-489f28848515'	System	21 Dec 2020 00:45:41
User entered 'No (N)'	System	21 Dec 2020 00:45:41

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D504CCAE-E6DB-4167-9537-1A05751E5636)', Time: '2020-12-20T16:45:39', User OID: 'PatientReportedOutcome (US3112223)', ODM File OID: '57b34aff-6148-4f6f-a961-489f28848515' User entered '20 Dec 2020 16:45:39'	System	21 Dec 2020 00:45:41
	System	21 Dec 2020 00:45:41

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:06:07

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

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)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

Please 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)	27 Apr 2021 03:33:42

US3112223

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:06:07

**US3112223**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:06:07
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:06:07

US3112223

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'No (N)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:07

US3112223

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:07

US3112223

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:07

US3112223

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:07

US3112223

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:18:02
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:12

US3112223

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	22 Dec 2020 21:54:12

US3112223

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:22

US3112223

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '22 Dec 2020'	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:22

US3112223

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:22

US3112223

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:22

US3112223

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Grande (b) (4)	22 Feb 2021 22:44:16
User entered 'Yes (Y)'	(b) (4)	
	Karen Mylerberg (b) (4)	22 Dec 2020 21:54:28
	(b) (4)	

**US3112223**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	22 Feb 2021 22:44:16
User entered 'I'	System	22 Dec 2020 21:54:28

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 05SEP2020 , 07SEP2020 , 09SEP2020 , 16SEP2020 and 19Sep2020 for Day 3, Day 5, Day 7, Day 9 and 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 10:42:57
User entered '03 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:48:11
User entered '10 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 18:46:49
Query 'Per GCL Lab Recon: Saliva: Samples dated 05SEP2020 , 07SEP2020 , 09SEP2020 , 16SEP2020 and 19Sep2020 for Day 3, Day 5, Day 7, Day 9 and 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 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:14:34
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 05SEP2020 , 07SEP2020 , 09SEP2020 , 16SEP2020 and 19Sep2020 for Day 3, Day 5, Day 7, Day 9 and 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)	28 Oct 2020 12:02:47
User entered '3 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:43:53

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:01:33
User entered '17:45' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:48:11
Query 'Data is required. Please complete.' answered with 'Confirmed unknown' (Site from System).	Matthew Musikanth (b) (4)	29 Oct 2020 18:46:58
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 18:46:49
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 18:46:49
User entered '19:35'	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:43:53

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Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '03 Sep 2020 17:45'	System	29 Oct 2020 20:48:11
User entered empty.	System	29 Oct 2020 18:46:49
User entered '3 Sep 2020 19:35'	System	10 Sep 2020 15:43:53

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:48:16
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 18:46:49
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:44:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:44:13
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	10 Sep 2020 15:44:13
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:43:53
User entered empty.	Karen Mylerberg (b) (4)	10 Sep 2020 15:43:53

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:43:53

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 1 (Day 1)'	(b) (4)	
	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36
	(b) (4)	

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:12:29
User entered '03 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 17:26:30
Query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' answered with 'as far as documented, yes' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:30:23
User opened query 'Per CDM: it appears both contact date and symptom start date are the same. Please confirm this date is the actual symptom start date and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:39:39
User entered '3 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99.3' F	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Mild (Mild)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:46:36

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 2 (Day 2)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:38:50
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '04 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '98'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Please verify why temperature not done as required per protocol.' (Site from CRA).	(b) (4)	
Query 'Please verify why temperature not done as required per protocol.' answered with 'Missed by site and patient.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 00:15:46
User opened query 'Please verify why temperature not done as required per protocol.' (Site from CRA).	Matthew Musikanth	02 Nov 2020 23:38:25
User entered missing code ND - Not Done.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 14:19:34
	Matthew Musikanth	12 Oct 2020 17:38:50
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Mild (Mild)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:38:50
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:38:50
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Mild (Mild)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:38:50

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 3 (Day 3)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:39:42
	(b) (4)	

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '05 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '98'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:39:42

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:39:42
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:39:42
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:39:42

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 7 (Day 7)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:41:00
	(b) (4)	

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '09 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:41:00
	(b) (4)	

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Form: Symptom Log (4)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:41:00

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:41:00
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:41:00
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:41:00

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 9 (Day 9)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '11 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '98'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:42:07

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 17:34:35
User entered 'Day 10 (Day 10)'	Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

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Form: Symptom Log (6)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '12 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:43:20

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:43:20
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:43:20

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 11 (Day 11)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:44:03
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '13 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:44:03

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:44:03
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:03

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 12 (Day 12)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:44:52
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '14 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:44:52
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	12 Oct 2020 17:44:52
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:44:52

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Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	29 Oct 2020 17:34:35
User entered 'Day 14 (Day 14)'	(b) (4)	
	Matthew Musikanth	12 Oct 2020 17:45:31
	(b) (4)	

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Form: Symptom Log (9)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '16 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '98'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

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Form: Symptom Log (9)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	12 Oct 2020 17:45:31

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Form: Symptom Log (9)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Oct 2020 17:45:31
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	12 Oct 2020 17:45:31

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 1 (Day 1)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '02 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '98'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '101.5' F	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:33:38

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'None (None)'	(b) (4) Matthew Musikanth	29 Oct 2020 17:33:38
	(b) (4)	

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Form: Symptom Log (11)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 5 (Day 5)'	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '6 Sep 2020'	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

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Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:45:26

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 6 (Day 6)'	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '7 Jan 2021'	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:17

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 7 (Day 7)'	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '8 Sep 2020'	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:46:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 9 (Day 9)'	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '10 Sep 2020'	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:47:42

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Day 14 (Day 14)'	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '15 Sep 2020'	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '%'	System	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:11:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Brenda Grande (b) (4)	28 Jan 2021 17:48:40

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
Query 'Per GCL Lab Recon: GCL has a SARS sample and a Nasopharyngeal swab dated 103Sep2020. No Illness visit has been completed matching this date, however, an Unschedule visit has been completed. Please reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Oct 2020 01:50:20
User opened query 'Per GCL Lab Recon: GCL has a SARS sample and a Nasopharyngeal swab dated 103Sep2020. No Illness visit has been completed matching this date, however, an Unschedule visit has been completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 01:47:01
User entered '3 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL Lab Recon: GCL has a SARS sample and a Nasopharyngeal swab dated 03Sep2020. No Illness visit has been completed matching this date, however, an Unschedule visit has been completed. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 04:39:45
Query 'Per GCL Lab Recon: GCL has a SARS sample and a Nasopharyngeal swab dated 03Sep2020. No Illness visit has been completed matching this date, however, an Unschedule visit has been completed. Please reconcile.' answered with 'updated unscheduled visit' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:29:30
User opened query 'Per GCL Lab Recon: GCL has a SARS sample and a Nasopharyngeal swab dated 03Sep2020. No Illness visit has been completed matching this date, however, an Unschedule visit has been completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 01:50:33
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Please confirm response as Day 3 Saliva collected 05Sep2020 and resulted 19Oct2020 shows a positive result in the Preclarus portal.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:39:38
Query 'Please confirm response as Day 3 Saliva collected 05Sep2020 and resulted 19Oct2020 shows a positive result in the Preclarus portal.' answered with 'Confirmed negative, D1 swab negative as well as previous in patient pcr results from day prior. ' (Site from CRA).	Matthew Musikanth (b) (4)	29 Oct 2020 17:36:52
User opened query 'Please confirm response as Day 3 Saliva collected 05Sep2020 and resulted 19Oct2020 shows a positive result in the Preclarus portal.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 04:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:29:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 16:29:09
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:29:09
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:51:52
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '3 Sep 2020'	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[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)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)'	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	Karen Mylerberg (b) (4)	10 Sep 2020 15:51:52

US3112223

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:25

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '0'	System	28 Oct 2020 16:29:09

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619519148 is reported with 03SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:19:31
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619519148 is reported with 03SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. ' answered with 'ppd updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 18:32:24
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619519148 is reported with 03SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 18:04:34
User entered '05 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Jan 2021 16:57:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:12:20

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'this is the correct date, source has the result from 3sep2020' (Site from DM).	Natalie Moy (b) (4)	17 Nov 2020 21:44:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:57:28
User entered '03 Sep 2020' reason for change: Data Entry Error	Natalie Moy (b) (4)	09 Nov 2020 17:56:25
User entered '05 Sep 2020'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:11:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	21 Jan 2021 15:59:05
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4)	07 Dec 2020 20:53:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 05SEP2020 is reported in PPD central lab with 19OCT2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:03:33
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 05SEP2020 is reported in PPD central lab with 19OCT2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'preclarus has been updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	29 Jan 2021 17:17:49
User entered '7 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Jan 2021 16:57:42
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 05SEP2020 is reported in PPD central lab with 19OCT2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:43:33
User entered '5 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 15:59:05
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07SEP2020 is recorded under Illness Visit Day 5 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 07:58:20

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07SEP2020 is recorded under Illness Visit Day 5 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 'updated' (Site from DM).	Natalie Moy (b) (4)	07 Dec 2020 20:53:36
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	07 Dec 2020 20:53:27
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07SEP2020 is recorded under Illness Visit Day 5 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). User entered '07 Sep 2020'	(b) (4), (b) (6)	07 Dec 2020 06:30:37
	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '09 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:11:25

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:11:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '11 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,19SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 08:56:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,19SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'site error for 19sep2020, sample collected on the 11th. ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 18:00:53
User entered '16 Sep 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 18:00:35
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,19SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:25:15
User entered '13 Sep 2020'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:11:25

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:11:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 06:13:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'no documentation of a saliva sample collected 19oct2020' (Site from DM).	Natalie Moy (b) (4) (b) (4)	07 Dec 2020 20:55:30
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 01:02:06
User entered empty.	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

**US3112223**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:43:46

US3112223

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response "Updated", however Saliva sample dated 19OCT2020 reported as Day5 sample is still missing. Please review the Preclarus data and update the EDC as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 06:44:06
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response "Updated", however Saliva sample dated 19OCT2020 reported as Day5 sample is still missing. Please review the Preclarus data and update the EDC as appropriate. Thank you.' answered with 'per source and lab report day 5 saliva was collected on 05SEP2020 with lab report being generated and reviewed on 19OCT2020' (Site from DM).	Brenda Grande (b) (4) (b) (4)	28 Jan 2021 17:22:43
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response "Updated", however Saliva sample dated 19OCT2020 reported as Day5 sample is still missing. Please review the Preclarus data and update the EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 06:10:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 19OCT2020 recorded for COVID PCR Saliva Day 5, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 06:10:51
Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 19OCT2020 recorded for COVID PCR Saliva Day 5, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:00:20

US3112223

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 19OCT2020 recorded for COVID PCR Saliva Day 5, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 15:50:57
	Matthew Musikanth	29 Oct 2020 17:41:09
	(b) (4)	

**US3112223**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:41:09

US3112223

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Clinic (Clinic)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:41:09

US3112223

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'SICKD1'	System	29 Oct 2020 17:41:09

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '19:35'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '03 Sep 2020 19:35'	System	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4)	
	Matthew Musikanth	29 Oct 2020 17:42:32
DataPoint set to visible.	(b) (4)	29 Oct 2020 17:41:09
	System	

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered missing code ND - Not Done.	(b) (4)	
	Matthew Musikanth	29 Oct 2020 17:42:32
DataPoint set to visible.	(b) (4)	29 Oct 2020 17:41:09
	System	

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '99.3' F	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:42:32
	(b) (4)	

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '86'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'bpm'	System	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '18'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'breaths/min'	System	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '126'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '80'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'mmHg'	System	29 Oct 2020 17:42:32

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:41:17

US3112223

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:41:17

US3112223

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:11:25

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:40

US3112223

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '03 Sep 2020'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:42:40

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:17

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:17
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:17
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'SICKD28'	System	29 Oct 2020 17:45:17

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:22
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:22
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:22
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:22
	(b) (4)	

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	29 Oct 2020 17:45:22

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:29

US3112223

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	29 Oct 2020 17:45:29
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:11:25

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	29 Oct 2020 17:45:33

US3112223

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:11:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	29 Oct 2020 17:45:33

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered empty.	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

**US3112223**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:25**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'I'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:37
User closed query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	30 Mar 2021 18:25:11
Query 'Was the participant unblinded is No however, data is present. Please reconcile.' answered by data change (Site from System).	System	30 Mar 2021 18:25:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	30 Mar 2021 18:25:11
User opened query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	30 Mar 2021 18:25:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	30 Mar 2021 18:25:04

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered '14 Jan 2021'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'Placebo (Placebo)'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'Placebo (Placebo)'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'Placebo (Placebo)'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:37
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	30 Mar 2021 18:25:04
	(b) (4)	

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	30 Mar 2021 18:25:04

US3112223

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	30 Mar 2021 18:25:04

US3112223

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:11:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:00:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Sep 2020 16:40:31

**US3112223**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:25**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:39:05
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:57:38
User entered 'USA-US062-2020-mRNA-1273-P301000001'	System	07 Sep 2020 18:57:13
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 18:57:13

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:15:30
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:25:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:25:42
Data point term sent to Coder	System	09 Sep 2020 22:40:23
Coding entries removed.	Matthew Musikanth (b) (4)	09 Sep 2020 22:39:46
User entered 'Strep-pharyngitis' reason for change: New Information	Matthew Musikanth (b) (4)	09 Sep 2020 22:39:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:10:40
Data point term sent to Coder	System	04 Sep 2020 17:09:36
User entered 'Fever'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:15:32
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:21
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:23
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:15:40
User entered '01 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Sep 2020 17:09:35
User entered '02 Sep 2020'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:19:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Oct 2020 21:39:01
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:39:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Sep 2020 19:42:34
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 03:10:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Sep 2020 04:10:28
User entered '00:00' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 04:10:28
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Unknown start time ' (Site from System).	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 17:08:36
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Sep 2020 17:08:36
User entered 'UN:UN' (non-conformant).	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	01 Oct 2020 21:39:01
User entered '01 Sep 2020 00:00'	System	06 Sep 2020 04:10:28
User entered '01 Sep 2020 UN:UN' (non-conformant).	System	04 Sep 2020 17:09:35
User entered '02 Sep 2020 UN:UN' (non-conformant).	System	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:19:23
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	28 Oct 2020 21:23:47
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 21:47:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 19:32:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Sep 2020 17:09:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:19:25
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	28 Oct 2020 21:28:04
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	28 Oct 2020 21:28:04
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	28 Oct 2020 21:23:47
User entered '14 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	28 Oct 2020 21:23:47
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)	20 Sep 2020 21:10:00
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	18 Sep 2020 21:47:04
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).	Matthew Musikanth (b) (4)	18 Sep 2020 19:32:34
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 19:32:20
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Sep 2020 19:32:20
User entered '14 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Sep 2020 19:32:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 19:31:53
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)	14 Sep 2020 16:07:23
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 17:09:56
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	04 Sep 2020 17:09:35
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	04 Sep 2020 17:09:35
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Sep 2020 17:09:35
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	04 Sep 2020 17:09:35
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	04 Sep 2020 17:08:36
User entered '03 Sep 2020'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:02:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:05
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 'will update when available' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:28:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:18:23
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Sep 2020 17:09:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 17:09:35
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	04 Sep 2020 17:09:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 17:08:36
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Sep 2020 17:08:36
User entered 'UN:UN' (non-conformant).	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	04 Sep 2020 17:09:35
User entered '03 Sep 2020 UN:UN' (non-conformant).	System	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:15:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:15:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:48
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:50
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

US3112223

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:34
User entered 'I'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:03:48
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'yes, as per narrative pt was hospitalized overnight' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 18:02:25
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:52:07
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 00:16:07
User entered '02 Sep 2020'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:16:09
User entered '03 Sep 2020'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

**US3112223**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:16:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:01
User entered empty.	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:02
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:04
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:05
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:16:53
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 00:17:00
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:23
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient plans to receive further IP doses, please update action taken to "none". If to remain as not applicable please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:05
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient plans to receive further IP doses, please update action taken to "none". If to remain as not applicable please explain.' answered with 'Updated, now that dose has been delayed. ' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:33:03
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Sep 2020 19:31:53
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Sep 2020 19:31:53
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient plans to receive further IP doses, please update action taken to "none". If to remain as not applicable please explain.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:08:22
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 00:17:01
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:41
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:19:59
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	01 Oct 2020 21:39:54
User entered '0' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:39:45
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 01:10:39
User entered '1'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:38
User entered '1' reason for change: Data Entry Error	Matthew Musikanth	01 Oct 2020 21:39:45
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:36
User entered '0'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'PV Query: Please provide the final outcome (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	28 Oct 2020 21:28:04
DataPoint Verified.	Matthew Musikanth (b) (4)	28 Oct 2020 21:28:04
Query 'PV Query: Please provide the final outcome (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'will updated when available' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 19:08:16
User opened query 'PV Query: Please provide the final outcome (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:31:03
User closed query 'PV Query: Please provide the final outcome (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)	28 Sep 2020 18:18:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Sep 2020 21:10:09
Query 'PV Query: Please provide the final outcome (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Recovered' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 21:47:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Sep 2020 19:33:14
	Matthew Musikanth (b) (4)	18 Sep 2020 19:31:53

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final outcome (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)	14 Sep 2020 16:07:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:08:14
User entered empty.	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per DM CLR: SAE Narrative = REPORTS FEVER, CHILLS, SORE THROAT AND MALAISE, ON 02SEP2020. However, please confirm if this should be reconciled with the start date of this AE. Review and update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 05:27:25
Query 'Per DM CLR: SAE Narrative = REPORTS FEVER, CHILLS, SORE THROAT AND MALAISE, ON 02SEP2020. However, please confirm if this should be reconciled with the start date of this AE. Review and update eCRF as appropriate. Otherwise, clarify. ' answered with 'symptoms began the 1sep2020 but became worse' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 18:02:51
User opened query 'Per DM CLR: SAE Narrative = REPORTS FEVER, CHILLS, SORE THROAT AND MALAISE, ON 02SEP2020. However, please confirm if this should be reconciled with the start date of this AE. Review and update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:27:04
User closed query 'Per DM CLR: SAE Narrative = HAD 3 NEG COVID TESTS IN ER.. However, these information were not recorded in the appropriate eCRF page (i.e., ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:55:19
User closed query 'PV Query: Please provide any relevant laboratory results (throat culture, WBC, CRP, etc).' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 19:02:20
User closed query 'PV Query: Please consider adding subject's history of Strep infection to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 19:02:16
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:53:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory results (throat culture, WBC, CRP, etc).'	Matthew Musikanth	28 Oct 2020 21:54:18
answered with 'Strep A PCR - Positive 03Sep2020 COVID 19 Rapid - Negative 02Sep2020 Influenza A/B PCR - Negative 02Sep2020 Blood Culture - No Growth 02Sep2020 WBC - 17.2 K/mcL 02Sep2020 Prelim. Abs Neut - 14.16 K/mcL 02Sep2020 Neutrophils - 82.6 K/mcL - 02Sep2020 Absolute Nuetrophils 14.16 K/mcL - 02Sep2020 IG# - 0.17 k/mcL - 02Sep2020 Absolute Monocytes 1.51 K/mcL - 02Sep2020  All other results within range.  ' (Site from Safety).	(b) (4)	
Query 'PV Query: Please consider adding subject's history of Strep infection to the Medical History eCRF.' answered with 'Not a history of chronic strep.' (Site from Safety).	Matthew Musikanth	28 Oct 2020 21:31:54
	(b) (4)	
Query 'Per DM CLR: SAE Narrative = HAD 3 NEG COVID TESTS IN ER.. However, these information were not recorded in the appropriate eCRF page (i.e., ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Updated, patient reported x3 covid tests, only 1 found in medical records' (Site from DM).	Matthew Musikanth	28 Oct 2020 21:28:44
	(b) (4)	
User opened query 'Per DM CLR: SAE Narrative = HAD 3 NEG COVID TESTS IN ER.. However, these information were not recorded in the appropriate eCRF page (i.e., ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 00:54:25
User opened query 'PV Query: Please provide any relevant laboratory results (throat culture, WBC, CRP, etc).'	(b) (4), (b) (6)	09 Oct 2020 14:54:49
(Site from Safety).		
User closed query 'PV Query: Please confirm if there was any treatment medications given for the event other than amoxicillin, which started on 10 Sep 2020. ) If yes, please add them to the Concomitant medications eCRF.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:34:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm Strep A antigen test performed on 03 Sep 2020 was positive. Please provide any other diagnostic test results if performed (throat culture, WBC, CRP, etc).' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:34:09
Query 'PV Query: Please confirm Strep A antigen test performed on 03 Sep 2020 was positive. Please provide any other diagnostic test results if performed (throat culture, WBC, CRP, etc).' answered with 'Confirmed per med records.' (Site from Safety).	Matthew Musikanth (b) (4)	01 Oct 2020 22:04:19
Query 'PV Query: Please confirm if there was any treatment medications given for the event other than amoxicillin, which started on 10 Sep 2020. If yes, please add them to the Concomitant medications eCRF.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	01 Oct 2020 22:01:11
User opened query 'PV Query: Please confirm if there was any treatment medications given for the event other than amoxicillin, which started on 10 Sep 2020. If yes, please add them to the Concomitant medications eCRF.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:19:49
User opened query 'PV Query: Please confirm Strep A antigen test performed on 03 Sep 2020 was positive. Please provide any other diagnostic test results if performed (throat culture, WBC, CRP, etc).' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:19:29
Query 'PV Query: Please consider adding subject's history of Strep infection to the Medical History eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:19:21
User opened query 'PV Query: Please consider adding subject's history of Strep infection to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:19:17
User opened query 'PV Query: Please consider adding subject's history of Strep infection to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:19:01
User closed query 'PV Query: Has the subject been exposed to anyone with strep or have any risk factors or other exposures for strep?' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results used to diagnose and monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:24

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm what "ST" was referring in ST+malaise.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:21
User closed query 'PV Query: Was there a plan for the subject to follow-up to monitor the course of the event.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:18
User closed query 'PV Query: Please confirm treatment was not provided for the event. If treatment was prescribed during or after the hospitalization, please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:10:15
Query 'PV Query: Please confirm treatment was not provided for the event. If treatment was prescribed during or after the hospitalization, please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:27
Query 'PV Query: Was there a plan for the subject to follow-up to monitor the course of the event.' answered with 'site F/U through illness visits, Patient to F/U with PCP after amoxicillin treatment' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:36:43
Query 'PV Query: Has the subject been exposed to anyone with strep or have any risk factors or other exposures for strep?' answered with 'Preexisting history of strep' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:36:09
Query 'PV Query: Please confirm what "ST" was referring in ST+malaise.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:35:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results used to diagnose and monitor the event. Please include units and reference ranges if applicable.' answered with 'Covid PCR screens - 02Sep2020 Strep A Antigen screen 03Sep2020' (Site from Safety).	Matthew Musikanth (b) (4)	18 Sep 2020 19:35:41
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Sep 2020 19:31:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Narrative](#)

Audit	User	Time (GMT)
User entered 'REPORTS FEVER, CHILLS, Sore throat and MALAISE, ON 02SEP2020. WENT TO ER AND ADMITTED OVERNIGHT. HAD 3 NEG COVID TESTS IN ER. Amoxicillian prescribed on discharge. Symptoms have since recovered.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Sep 2020 19:31:53
User opened query 'PV Query: Please confirm treatment was not provided for the event. If treatment was prescribed during or after the hospitalization, please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:09:19
User opened query 'PV Query: Was there a plan for the subject to follow-up to monitor the course of the event.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:09:05
User opened query 'PV Query: Has the subject been exposed to anyone with strep or have any risk factors or other exposures for strep?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:08:51
User opened query 'PV Query: Please confirm what "ST" was referring in ST+malaise.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:08:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results used to diagnose and monitor the event. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:07:50
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 00:17:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Sep 2020 18:55:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Sep 2020 18:55:24
User entered 'Reports fever, chills, ST+malaise, on 02Sep2020. Went to ER and admitted overnight. Had 3 neg COVID tests in ER. No meds at discharge. Will obtain medical records for dx and workup.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Sep 2020 18:55:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Sep 2020 17:08:36
User entered empty.	Matthew Musikanth (b) (4)	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	04 Sep 2020 17:08:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered 'I'	System	04 Sep 2020 17:08:36

**US3112223**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '0'	System	04 Sep 2020 17:08:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:11:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:53:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:13:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:54:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:17:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:17:29
Data point term sent to Coder	System	19 Aug 2020 16:15:57
User entered 'Crestor'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Hypercholesterol'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '20'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:15:52
User entered 'UN UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:15:52

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:15:52

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:15:52

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:41:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:22:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:22:50
Data point term sent to Coder	System	01 Oct 2020 21:21:32
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	01 Oct 2020 21:20:55
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Updated' (Site from System).	Matthew Musikanth (b) (4)	01 Oct 2020 21:20:55
User entered 'PLAVIX' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:20:49
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Sep 2020 05:05:31
Data point term sent to Coder	System	19 Aug 2020 16:16:58

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Plavis'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 11:57:07
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'updated ,ed hx' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:19:00
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:43:52
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 03:49:07
Query 'Per DM CLR : Please confirm if this Con Med was given for MH #3 (CARDIAC STENT). If yes, please review MH term and update to reflect a match with this medical condition. Update Con Med eCRF and Med History eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 03:48:45
User opened query 'Per DM CLR : Please confirm if this Con Med was given for MH #3 (CARDIAC STENT). If yes, please review MH term and update to reflect a match with this medical condition. Update Con Med eCRF and Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 03:48:24
User entered 'Cad S/P Stent'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '75'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:16:39
User entered 'UN UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:16:39

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:16:39

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:16:39

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:16:39

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:42:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:19:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:19:34
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	19 Aug 2020 16:18:04 19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Cardiac Prophylaxis'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '81'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:17:14
User entered 'UN UNK 2017'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:17:14

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:17:14

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:17:14

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:17:14

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:42:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:19:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:19:34
Data point term sent to Coder	System	19 Aug 2020 16:19:08
User entered 'Allopurinol'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Query 'Per DM CLR: Please review Indication and please update to specify the location of manifestation of Gout and please ensure that there is a corresponding MH record for this condition. Please update applicable details as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:54:49
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of manifestation of Gout and please ensure that there is a corresponding MH record for this condition. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 03:59:17
User entered 'Gout'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '300'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:11:25**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:19:04
User entered 'UN UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:19:04

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:19:04

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:19:04

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:19:04

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:42:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:21:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:21:23
Data point term sent to Coder	System	19 Aug 2020 16:20:15
User entered 'Magnesium'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Health Supplement'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '1000'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:19:51
User entered '01 Jan 2020'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:19:51

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:19:51

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:19:51

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:19:51

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: OTHER INTESTINAL ANTIINFECTIVES, PRODUCT: BERBERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:48:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:48:09
Data point term sent to Coder	System	19 Aug 2020 16:21:20
User entered 'Berberine'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Health Supplement'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '600'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:21:03
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

**US3112223**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:11:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:21:03

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2'	System	19 Aug 2020 16:21:03

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:21:03

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:21:03

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN, PRODUCTSYNONYM: DIOVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:23:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:23:31
Data point term sent to Coder User entered 'Diovan'	System (b) (4), (b) (6)	19 Aug 2020 16:22:21 19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Hypertension'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '320'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:10:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:21:42
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 16:21:42

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:21:42

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	19 Aug 2020 16:21:42

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	19 Aug 2020 16:21:42

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:05:41
Data point term sent to Coder	System	18 Sep 2020 19:38:53
User entered 'Amoxicillin'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Strepp-Pharyngitis'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '500'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered empty.	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:45
User closed query 'Please confirm start date. Please refer to conmed log and medical records.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 21:38:12
Query 'Please confirm start date. Please refer to conmed log and medical records.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:24
DataPoint Un-verified.	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:18
User entered '02 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:18
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:43:52
User opened query 'Please confirm start date. Please refer to conmed log and medical records.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:16:33
User entered '10 Sep 2020'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '0'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

**US3112223**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:11:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered '14 Sep 2020'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:43:52
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Sep 2020 19:38:11

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '2'	System	18 Sep 2020 19:38:11

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	18 Sep 2020 19:38:11

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	18 Sep 2020 19:38:11

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:00:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:00:58
Data point term sent to Coder	System	01 Oct 2020 22:00:32
User entered 'Acetaminophen'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:16:02
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'This medication is taken during hospitalization of reported SAE' (Site from DM).	Matthew Musikanth (b) (4)	02 Nov 2020 23:37:35
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:39:30
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'Fever reduction'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered '1000'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered '02 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered '0'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:18
User entered '02 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 23:37:16
DataPoint Un-verified.	Matthew Musikanth (b) (4)	02 Nov 2020 23:36:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 23:36:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:00:18
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 22:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 22:00:03
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Oct 2020 22:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:59:58
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 21:59:58

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	01 Oct 2020 21:59:58

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	01 Oct 2020 21:59:58

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	01 Oct 2020 21:59:58

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:43
Data point term sent to Coder	System	28 Oct 2020 16:24:40
User entered 'flu vaccine'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'influenza virus prophylaxis'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered '0.5'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'mL (mL)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'once (ONCE)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'Intramuscular (INTRAMUSCULAR)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered '19 Oct 2020'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered '0'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered '19 Oct 2020'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:16
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:24:29

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:24:29

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered empty.	System	28 Oct 2020 16:24:29

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:48:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:53
Data point term sent to Coder	System	28 Oct 2020 16:25:41
User entered 'Losartan'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'hypertension'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered '100'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'once daily (QD)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'un UNK 2010'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered '0'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:27
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 16:25:21
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:21
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:25:12
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:25:12

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	28 Oct 2020 16:25:12

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	28 Oct 2020 16:25:12

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	28 Oct 2020 16:25:12

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:48:20
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: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:43:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:43:06
Data point term sent to Coder	System	28 Oct 2020 16:27:48
User entered 'valtrex'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'herpes simplex virus'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Un-verified.	Natalie Moy (b) (4)	09 Nov 2020 18:03:50
User entered '2000' reason for change: Data Entry Error	Natalie Moy (b) (4)	09 Nov 2020 18:03:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered '1000'	Natalie Moy (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (1000 ug) of this medication. Please review unit and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 05:30:47
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (1000 ug) of this medication. Please review unit and update as applicable. ' answered with 'updated per pt chart' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 18:04:17
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (1000 ug) of this medication. Please review unit and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:02:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'ug (ug)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'once daily (QD)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'un UNK 2010'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered '0'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered empty.	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:49:29
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	28 Oct 2020 16:27:38

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:11:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	28 Oct 2020 16:27:38

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '1'	System	28 Oct 2020 16:27:38

US3112223

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:11:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '804 (804)'	System	28 Oct 2020 16:27:38

US3112223

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:11:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:36:25
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Oct 2020 21:24:06

US3112223

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:25

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:21
User entered '02 Sep 2020'	Matthew Musikanth (b) (4)	28 Oct 2020 21:27:15

US3112223

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:21
User entered 'In-Patient Covid PCR'	Matthew Musikanth (b) (4)	28 Oct 2020 21:27:15

US3112223

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:36:21
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	28 Oct 2020 21:27:15

US3112223

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:25

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:36:21
User entered empty.	Matthew Musikanth (b) (4)	28 Oct 2020 21:27:15

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '14 Jan 2021'	(b) (4) Matthew Musikanth	14 Jan 2021 23:10:14
	(b) (4)	

**US3112223**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:11:25**

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	14 Jan 2021 23:10:14

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

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 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'Request to unblind/ EUA COVID-19 Vaccine'	Matthew Musikanth (b) (4)	14 Jan 2021 23:10:14

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	14 Jan 2021 23:10:14

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	14 Jan 2021 23:10:14

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth	14 Jan 2021 23:10:14
	(b) (4)	

US3112223

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:25

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	14 Jan 2021 23:10:14

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
User entered '07/Sep/2020 14:58'	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:11:25

**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)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
User entered '10/Sep/2020 21:39'	System	11 Sep 2020 01:39:37

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:11:25

**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)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 01:39:37

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
User entered '20/Sep/2020 17:11'	System	20 Sep 2020 21:11:08

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:11:25

**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)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:34:20
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:38:15
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 21:11:08

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:04
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '02/Oct/2020 08:34'	(b) (4) System	02 Oct 2020 12:34:27

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:11:25

**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)	27 Apr 2021 03:33:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:04
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 19:02:30
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:34:27

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'USA-US062-2020-MRNA-1273-P301000001'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'Yes (Y)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 18:58:45
User entered 'No (N)'	System	07 Sep 2020 18:57:13

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Laurie'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'Han-Conrad'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '9040 Friars Rd St 540'	System	14 Sep 2020 21:51:14
User entered '9040 Friars Road'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'San Diego'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
User entered 'CA'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:10:58
Amendment Manager: User entered '92108'	System	14 Sep 2020 21:51:14
User entered '92119'	Karen Mylerberg (b) (4) (b) (4)	14 Sep 2020 00:43:49

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:38:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 01:39:23
User entered 'US' (non-conformant).	System	07 Sep 2020 18:58:51

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
User entered '5'	System	29 Oct 2020 19:02:42
User entered '4'	System	02 Oct 2020 12:34:27
User entered '3'	System	20 Sep 2020 21:11:08
User entered '2'	System	11 Sep 2020 01:39:37
User entered '1'	System	07 Sep 2020 18:58:51

**US3112223**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:11:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 03:33:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:04
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered '29/Oct/2020 19:02'	(b) (4) System	29 Oct 2020 19:02:42

US3112223

Folder: SAE USA-US062-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:11:25

**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)	27 Apr 2021 03:33:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:23:04
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:52
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 19:02:42