

US3312225 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:04:11

All time stamps listed in this document are displayed in GMT

US3312225

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

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Participant ID

US3312225

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

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US3312225

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 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) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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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) 15 Feb 2021 22:20:42

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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) 15 Feb 2021 22:20:42

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	HYPERLIPIDEMIA
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)	

US3312225

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	HYPERTENSION
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 (5)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2018
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)	24 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 22:20:42

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	HYPOTESTOSTERONISM
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)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Condition	HEARTBURN
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)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:15 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:15
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	252 lb
BMI ( <i>xxx.x</i> )	35.22036 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" 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) 15 Feb 2021 22:20:42

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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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) 15 Feb 2021 22:20:42

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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)	False
<b>Other</b>	True
<b>Specify</b>	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144483

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) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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)	24 AUG 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:15
Temperature (xxx.x)	98.4 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)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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)	24 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:05
Temperature (xxx.x)	97.3 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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) 15 Feb 2021 22:20:42

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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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 10:29 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 10:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:54	24 AUG 2020 09:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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 17:04:11

**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

97.3 °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

24 AUG 2020 11:07

PC Open Date & Time

24 AUG 2020 10:49

PC Close Date & Time

24 AUG 2020 13:19



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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 94.3 °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	24 AUG 2020 19:32
PC Open Date & Time	24 AUG 2020 14:14
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 19:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**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

93.0 °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

26 AUG 2020 19:39

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 06:40

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**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

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:14

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**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

93.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 20:51

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

---

**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

94.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 20:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 11:08

PC Open Date & Time

24 AUG 2020 10:49

PC Close Date & Time

24 AUG 2020 13:19



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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

24 AUG 2020 19:33

PC Open Date & Time

24 AUG 2020 14:14

PC Close Date & Time

25 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**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

25 AUG 2020 19:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**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

26 AUG 2020 19:40

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**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

28 AUG 2020 06:41

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:15

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**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

29 AUG 2020 20:51

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**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 AUG 2020 20:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**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 ☐



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 11:09
PC Open Date & Time	24 AUG 2020 10:49
PC Close Date & Time	24 AUG 2020 13:19

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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 ☐

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 19:33
PC Open Date & Time	24 AUG 2020 14:14
PC Close Date & Time	25 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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 ☒

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:03
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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 3171

EAB) (1725)

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 19:40
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3171

EAB) (1725)



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 06:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

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EAB) (1725)

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:15
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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 ☒

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 20:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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 ☒

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:58
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3312225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312225

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:29 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:29
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)	90 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)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:17
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3312225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 09:46

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

What was the frequency of the study treatment dosing? ONCE

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

US3312225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	09:14 (24 HR)
Collection date and time (derived)	21 SEP 2020 09:14

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	21 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

US3312225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 10:21

PC Open Date & Time

21 SEP 2020 10:06

PC Close Date & Time

21 SEP 2020 12:36

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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

94.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	21 SEP 2020 18:35
PC Open Date & Time	21 SEP 2020 13:31
PC Close Date & Time	22 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 05:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**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

93.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 07:42

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 09:40

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**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.

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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

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 07:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**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.

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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

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 10:21

PC Open Date & Time

21 SEP 2020 10:06

PC Close Date & Time

21 SEP 2020 12:36

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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

21 SEP 2020 18:35

PC Open Date & Time

21 SEP 2020 13:31

PC Close Date & Time

22 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**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

23 SEP 2020 05:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 07:42

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 09:40

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 07:25

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**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 ☐

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:22
PC Open Date & Time	21 SEP 2020 10:06
PC Close Date & Time	21 SEP 2020 12:36

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**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 ☐



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 18:35
PC Open Date & Time	21 SEP 2020 13:31
PC Close Date & Time	22 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**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 ☒

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 05:40
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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 ☒

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 07:42
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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 ☒

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 09:41
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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 ☐



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 07:25
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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 ☐

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312225

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:55

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	08:17 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:17
Temperature (xxx.x)	97.9 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

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.*

US3312225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	08:29 (24 HR)
Collection date and time (derived)	19 OCT 2020 08:29

US3312225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:20:42

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 14:50:52
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**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

02 NOV 2020 18:42:31

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

09 NOV 2020 09:33:24

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2020 23:59
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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 19:13:27
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**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

17 DEC 2020 10:23:33

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 16:43:56
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**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

30 DEC 2020 19:56:11

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 08:26:05

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 16:00:10

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 12:57:42

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 08:29:33

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 16:21:36

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 18:11:02

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 10:34:47
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 10:32:27

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 22:15:44

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 16:50:08

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 14:13:03

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 15:01:16
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 15:15:52
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 08:02:08

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 11:41:55

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59
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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3312225

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 MAY 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

28 AUG 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 2022 23:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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



**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

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US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312225**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

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

US3312225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:04:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 10:34:36

US3312225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:44

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 20:40:42

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 20:40:42

Generated On: 09 Jun 2021 17:04:11

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) \_\_\_\_\_



US3312225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 20:40:42

Generated On: 09 Jun 2021 17:04:11

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.*

US3312225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 20:40:41

Generated On: 09 Jun 2021 17:04:11

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3312225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:40:41

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 20:40:41

Generated On: 09 Jun 2021 17:04:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312225

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:40:40

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312225

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

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*

US3312225

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Date of Contact	09 NOV 2020
Time of Contact	08:00
Date and Time of Contact (derived)	09 NOV 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (5)

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Generated On: 09 Jun 2021 17:04:11

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

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (6)

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (7)

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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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Form: Symptom Log (7)

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Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	100.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" 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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Generated On: 09 Jun 2021 17:04:11

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

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Form: Symptom Log (8)

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Generated On: 09 Jun 2021 17:04:11

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

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Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 09 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.7 F
-------------	--------

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

Cough	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (9)

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Generated On: 09 Jun 2021 17:04:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input 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 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 type="radio"/>
	Mild	<input checked="" 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 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	102.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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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Form: Symptom Log (11)

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Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 21:26:42

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	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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Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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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Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 21:26:42

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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 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	101.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

Date	18 NOV 2020
------	-------------

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

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

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

Temperature	97.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

Date	20 NOV 2020
------	-------------

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

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

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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"/>

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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

Date	21 NOV 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

Symptom Day

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

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

	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 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 21:26:42

Generated On: 09 Jun 2021 17:04:11

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 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Date of Visit	09 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	09 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 21:25:58

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Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:04:11

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	15 NOV 2020
Day 9	Yes	17 NOV 2020
Day 14	Yes	22 NOV 2020
Day 21	No	
Day 28	Yes	07 DEC 2020

US3312225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 NOV 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	09 NOV 2020 09:20
Height (xxx.x)	71 in
Weight (xxx.x)	244.4 lb
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312225

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 NOV 2020

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

US3312225

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 NOV 2020

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 DEC 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	07 DEC 2020 11:25
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 DEC 2020

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

US3312225

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:04:11

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 DEC 2020

US3312225

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312225

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Date of updated informed consent ( <i>dd MMM yyyy</i> )	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	28 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	

US3312225

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	08:42 (24 HR)
Collection date and time (derived)	28 JAN 2021 08:42

US3312225

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	08:41
Collection Date and Time (derived)	28 JAN 2021 08:41

US3312225

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

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*



**US3312225**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:04:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312225

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:52:08

Generated On: 09 Jun 2021 17:04:11

---

Did the participant experience any adverse events?

Yes ☒  
No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 16:55:54

Generated On: 09 Jun 2021 17:04:11

AEID	USA-US300-2020-MRNA-1273-P30 1000011
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 16:55:54

Generated On: 09 Jun 2021 17:04:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 16:55:54

Generated On: 09 Jun 2021 17:04:11

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SUBJECT CALLED CLINIC AT  
0800 THIS MORNING TO  
REPORT COVID SYMPTOMS  
AND A POSITIVE COVID-19  
TEST IN THE ED LAST NIGHT.  
HE REPORTS THAT HE CALLED  
HIS PCP ON 08 NOV 2020 WITH  
SYMPTOMS AND WAS  
INSTRUCTED TO GO TO THE  
LOCAL ED FOR TESTING. IN  
THE ED, SUBJECT HAD A  
NEGATIVE CXR AND WAS  
INSTRUCTED TO TAKE  
PRESCRIBED  
DEXAMETHASONE, AS WELL  
AS OTC ZINC, CALCIUM, AND  
VITAMIN D. AT ILLNESS VISIT  
TODAY, SUBJECT REPORTS  
SYMPTOM ONSET ON 04 NOV  
2020 WITH MILD CHILLS,  
COUGH, MUSCLE ACHES, BODY  
ACHES, HEADACHE, AND  
FATIGUE. HE REPORTS BEING  
AFEBRILE APART FROM TMAX  
OF 100.7 F ON 07 NOV 2020.  
SUBJECT ALSO REPORTS TWO  
EPISODES OF LOOSE STOOL,  
ONE ON 06 NOV 2020, AND THE  
OTHER ON 07 NOV 2020.  
REPORTS RUNNY NOSE FROM  
06 NOV 2020 TO 08 NOV 2020.  
SUBJECT ALSO REPORTS MILD  
SHORTNESS OF BREATH  
BEGINNING TODAY, SPO2 100%  
TODAY. OTHER VITAL SIGNS  
AND PHYSICAL EXAM  
UNREMARKABLE AS WELL.  
ACETAMINOPHEN TAKEN  
YESTERDAY FOR MUSCLE  
ACHES, BODY ACHES, AND  
HEADACHE. SUBJECT REPORTS  
NO KNOWN SICK CONTACTS IN  
RECENT WEEKS.

---

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 16:55:54

Generated On: 09 Jun 2021 17:04:11

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

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AEID	USA-US300-2021-MRNA-1273-P30 1000012
Adverse event	TRANSIENT ISCHEMIC ATTACK
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)	24 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 16:55:54

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SUBJECT IS A 54 YEAR OLD GENTLEMAN WITH H/O ATHEROSCLEROSIS (S/P BYPASS SURGERY), HYPERLIPIDEMIA, HTN, HYPOTHYROIDISM AND SYMPTOMATIC COVID-19 IN NOVEMBER 2020 WHO AT HIS DECISION VISIT ON 1/28/2021 REPORTED TRANSIENT MEMORY LOSS AND SPEECH DISTURBANCES ON 1/24/2021. HE HAD BEEN INSTRUCTED BY HIS PCP TO GO TO ED, BUT HE REFUSED AND WAS SEEN BY PCP THE NEXT DAY, ON 1/25/2021. PCP'S OFFICE VISIT MEDICAL RECORDS SHOW THAT HE HAD A NORMAL EXAM WITH FINAL ASSESSMENT OF TRANSIENT ISCHEMIC ATTACK (TIA); FURTHER EVALUATIONS WERE ORDERED, INCLUDING CAROTID DOPPLER (WHICH PER SUBJECT'S VERBAL REPORT ON 2/4/21 WAS NORMAL) AND MRA/MRI WHICH IS YET TO BE COMPLETED. CLOPIDOGREL 75MG PO DAILY WAS ADDED TO HIS DAILY MEDICATION REGIMEN WHICH ALREADY INCLUDED ASPIRIN 81MG PO DAILY. ALTHOUGH SUBJECT

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 16:55:54

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REPORTED SYMPTOMS ON  
1/28/2021, EVENT NOT  
DETERMINED TO BE SAE UNTIL  
REVIEW OF MEDICAL RECORDS  
ON 2/3/2021 AND DISCUSSION  
WITH PI ON 2/4/2021. THIS IS AN  
SAE FOR A MEDICALLY  
IMPORTANT EVENT OF TIA,  
NOT RELATED TO IP. WILL  
CLOSE AFTER REVIEW OF  
DIAGNOSTIC PROCEDURE  
RESULTS

---

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)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 16:55:54

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AEID	
Adverse event	WORSENING HYPERLIPIDEMIA
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)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication REPATHA (EVOLOCUMAB)

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 140

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

EVERY 15 DAYS

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) 09 Apr 2021 16:55:55

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	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)	_____	
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 (2)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication INSULIN DEGLUDEC

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 50

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 (3)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOVASCULAR  
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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) 09 Apr 2021 16:55:55

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	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)	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 (6)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 145

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) 09 Apr 2021 16:55:55

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	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 (7)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify MCG

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) 09 Apr 2021 16:55:55

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	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 (9)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES MELLITUS

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) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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)	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 (10)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA  
VACCINE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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) 09 Apr 2021 16:55:55

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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)	26 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)		26 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) 09 Apr 2021 16:55:55

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYPTOMATIC COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 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 (12)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 4000

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) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

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 (13)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 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 (14)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication CALCIUM CITRATE 630MG/ D3  
12.5MG

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 2

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 (14)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 6

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 (15)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication ZINC

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

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 (16)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication ERYTHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication HYDROXYCHLOROQUINE

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 16:55:55

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	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication TRANSIENT ISCHAEMIC  
ATTACK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication CLINDAMYCIN 1%

Prophylaxis Yes ☒  
No ☐

Indication PREVENT RASH AFTER  
HAIRCUT

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (20)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTESTOSTERONEMIA

Dose per administration 120

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 (21)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 (22)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication UBIQUINONE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 (23)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF  
HYPERLIPIDEMIA

Dose per administration 80

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 (23)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 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 (24)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication EMPAGLIFLOZIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 25

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 (24)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 (25)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication ICOSAPENT

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF  
HYPERLIPIDEMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 OCT 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)	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 (26)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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 (26)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (27)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

Name of Medication CALCIUM CARBONATE

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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 (27)

Data signed: (b) (4) 09 Apr 2021 16:55:55

Generated On: 09 Jun 2021 17:04:11

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:04:11

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:04:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:04:11

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

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Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 18:19
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



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/NOV/2020 10:11
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

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/NOV/2020 17:57
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

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/DEC/2020 08:49
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

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/FEB/2021 12:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/FEB/2021 12:54
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

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 14:22
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

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 13:31
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



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/MAR/2021 10:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:26:43

Generated On: 09 Jun 2021 17:04:11

SAEID	USA-US300-2021-MRNA-1273-P301000012
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 10:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312225 (Prod: Johnson County Clin-Trials)

**US3312225**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:04:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'US3312225'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:39:26

US3312225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:17

US3312225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:39:27

US3312225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	24 Aug 2020 15:40:17

US3312225

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'SCRN'	System	24 Aug 2020 15:40:17



US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:39:28

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 11:02:38
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:48
User entered '54'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 06:52:46

**US3312225**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:04:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'YEARS'	System	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '54'	System	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44



US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:04:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:44

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:30



US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Aug 2020'	System	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2020'	System	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:30

US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:39:27



US3312225

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:04:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'I'	System	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:04:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:41:55

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Atherosclerosis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:50
Data point term sent to Coder	System	01 Sep 2020 15:43:37
User entered 'atherosclerosis'	Karol Moore (b) (4)	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:42:56



US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:42:56

**US3312225**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:04:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:42:56

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Surgical and medical procedures, HLT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Quadruple vessel bypass graft - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:49
Data point term sent to Coder	System	01 Sep 2020 15:43:39
User entered 'quadruple bypass surgery'	Karol Moore (b) (4)	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:19



US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:43:19

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:44:49
Data point term sent to Coder	System	01 Sep 2020 15:43:40
User entered 'hyperlipidemia'	Karol Moore (b) (4)	01 Sep 2020 15:43:35



US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:35

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:35

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Barker (b) (4)	23 Oct 2020 14:18:22
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	01 Sep 2020 15:43:35
	(b) (4)	

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	Heather Barker (b) (4)	23 Oct 2020 14:18:22
	(b) (4)	
User entered 'un UNK 2010'	Karol Moore (b) (4)	01 Sep 2020 15:43:35
	(b) (4)	

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:35

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:43:35

US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:43:35

**US3312225**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:04:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	23 Oct 2020 14:18:22
User entered 'Jan 2010'	System	01 Sep 2020 15:43:35



US3312225

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	23 Oct 2020 14:18:22
User entered '2010'	System	01 Sep 2020 15:43:35

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:45:53
Data point term sent to Coder	System	01 Sep 2020 15:44:40
User entered 'hypertension'	Karol Moore (b) (4)	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Heather Barker (b) (4)	23 Oct 2020 14:18:49
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	01 Sep 2020 15:43:49
	(b) (4)	

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	Heather Barker (b) (4)	23 Oct 2020 14:18:49
User entered 'un UNK 2010'	(b) (4)	
	Karol Moore (b) (4)	01 Sep 2020 15:43:49
	(b) (4)	

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2010'	System	01 Sep 2020 15:43:49



US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2010'	System	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	23 Oct 2020 14:18:49
User entered 'Jan 2010'	System	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	23 Oct 2020 14:18:49
User entered '2010'	System	01 Sep 2020 15:43:49

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:49:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:49:16
Data point term sent to Coder	System	01 Sep 2020 15:47:46
User entered 'hypothyroidism'	Karol Moore (b) (4)	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	01 Sep 2020 15:48:07
User entered '24 Aug 2020' reason for change: Data Entry Error	System	01 Sep 2020 15:48:07
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Karol Moore (b) (4)	01 Sep 2020 15:48:07
User entered '24 Aug 2002'	(b) (4)	01 Sep 2020 15:47:22
	System	01 Sep 2020 15:47:22
	Karol Moore (b) (4)	01 Sep 2020 15:47:22
	(b) (4)	



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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2018'	System	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2018'	System	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Aug 2020'	System	01 Sep 2020 15:48:07
User entered 'Aug 2002'	System	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2020'	System	01 Sep 2020 15:48:07
User entered '2002'	System	01 Sep 2020 15:47:22

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:48:43
Data point term sent to Coder	System	01 Sep 2020 15:47:46
User entered 'diabetes mellitus type ii'	Karol Moore (b) (4)	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:40



US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2018'	System	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2018'	System	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	01 Sep 2020 15:47:40

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:49:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 15:49:46
Data point term sent to Coder	System	01 Sep 2020 15:48:47
User entered 'allergy to penicillin'	Karol Moore (b) (4)	01 Sep 2020 15:47:54



US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 1982'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 1982'	System	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '1982'	System	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	01 Sep 2020 15:47:54



**US3312225**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:04:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	01 Sep 2020 15:47:54

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:35:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:35:48
Data point term sent to Coder	System	05 Feb 2021 20:35:00
User entered 'vitamin d deficiency'	(b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2017'	System	05 Feb 2021 20:34:19



US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2017'	System	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:34:19

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Endocrine disorders, HLG: Endocrine disorders of gonadal function, HLT: Male gonadal function disorders, PT: Androgen deficiency, LLT: Hypotestosteronism - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:36:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:36:49
Data point term sent to Coder	System	05 Feb 2021 20:36:01
User entered 'hypotestosteronism'	(b) (4), (b) (6)	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:35:16



US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2015'	System	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2015'	System	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:35:16

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 20:37:55
Data point term sent to Coder	System	05 Feb 2021 20:37:02
User entered 'heartburn'	(b) (4), (b) (6)	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:36:17



US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'Jan 2015'	System	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '2015'	System	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered empty.	System	05 Feb 2021 20:36:17

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50



US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:15' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:31:42
User entered '9:15'	Karol Moore (b) (4)	01 Sep 2020 15:48:50
	(b) (4)	

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '24 Aug 2020 09:15'	System	15 Sep 2020 00:31:42
User entered '24 Aug 2020 9:15'	System	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '71' in	(b) (4) Karol Moore (b) (4)	01 Sep 2020 15:48:50
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '252' lb	(b) (4) Karol Moore (b) (4)	01 Sep 2020 15:48:50
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered '35.22036'	System	01 Sep 2020 15:48:50
DataPoint set to visible.	System	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'kg/m2'	System	01 Sep 2020 15:48:50
DataPoint set to visible.	System	24 Aug 2020 15:40:36

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50



US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'bpm'	System	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'breaths/min'	System	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'mmHg'	System	01 Sep 2020 15:48:50



US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User entered 'mmHg'	System	01 Sep 2020 15:48:50

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03

US3312225

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03

US3312225

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:49:41

US3312225

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:49:41

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44



US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	Karol Moore (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	Karol Moore (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44



US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	Karol Moore (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	Karol Moore (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

**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 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44



US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:04:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:05:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:50:44

US3312225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:53

US3312225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:40:53

US3312225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	24 Aug 2020 15:40:53

US3312225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'VISIT1'	System	24 Aug 2020 15:40:53

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 15:09:58



US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '144483'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 15:09:58

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 15:09:58

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	Christa Estrada (b) (4)	24 Aug 2020 15:41:06

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	Christa Estrada (b) (4)	24 Aug 2020 15:41:06

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:06

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:06

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:06

US3312225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 18:05:07
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:25:41



US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	01 Sep 2020 15:53:29
	(b) (4)	

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:15' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:31:51
User entered '9:15'	Karol Moore (b) (4)	01 Sep 2020 15:53:29
	(b) (4)	



US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '24 Aug 2020 09:15'	System	15 Sep 2020 00:31:51
User entered '24 Aug 2020 9:15'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '98.4' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '74'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'bpm'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'breaths/min'	System	01 Sep 2020 15:53:29



US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '132'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'mmHg'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'mmHg'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:04:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29



US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:30:53
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:25:49
User entered '11:05'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '24 Aug 2020 11:05'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '97.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '86'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'bpm'	System	01 Sep 2020 15:53:29



US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'breaths/min'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '122'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'mmHg'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '85'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'mmHg'	System	01 Sep 2020 15:53:29

US3312225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:38

US3312225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:53:38



US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	Christa Estrada (b) (4)	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '10:29'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '24 Aug 2020 10:29'	System	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:41:33



US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'ONCE'	System	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 15:41:33

US3312225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:02

US3312225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:02

US3312225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:59' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:31:58
User entered '9:59'	Karol Moore (b) (4)	01 Sep 2020 15:54:02
	(b) (4)	

US3312225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '24 Aug 2020 09:59'	System	15 Sep 2020 00:31:58
User entered '24 Aug 2020 9:59'	System	01 Sep 2020 15:54:02

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:04:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18



US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:54' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:32:05
User entered '9:54'	Karol Moore (b) (4)	01 Sep 2020 15:54:18
	(b) (4)	

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '24 Aug 2020 09:54'	System	15 Sep 2020 00:32:05
User entered '24 Aug 2020 9:54'	System	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered empty.	System	01 Sep 2020 15:54:18

US3312225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4)	01 Sep 2020 15:54:22
	Karol Moore (b) (4)	
	(b) (4)	



US3312225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered '1'	System	01 Sep 2020 15:54:22

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T10:49:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '557aac05-ab91-4f80-9a6a-96e3e8473165'	System	24 Aug 2020 16:07:54
User entered 'Yes (Y)'	System	24 Aug 2020 16:07:54

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:07:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '557aac05-ab91-4f80-9a6a-96e3e8473165'	System	24 Aug 2020 16:07:54
User entered '97.3'	System	24 Aug 2020 16:07:54

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:07:45', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '557aac05-ab91-4f80-9a6a-96e3e8473165'	System	24 Aug 2020 16:07:54
User entered 'No (N)'	System	24 Aug 2020 16:07:54

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:07:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '557aac05-ab91-4f80-9a6a-96e3e8473165'	System	24 Aug 2020 16:07:54
User entered '24 Aug 2020 11:07'	System	24 Aug 2020 16:07:54

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 10:49'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 13:19'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:30:29', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'f08a5224-4a59-4bea-acd3-b1410546d97c'	System	25 Aug 2020 00:33:03
User entered 'Yes (Y)'	System	25 Aug 2020 00:33:03

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:32:50', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'f08a5224-4a59-4bea-acd3-b1410546d97c'	System	25 Aug 2020 00:33:03
User entered '94.3'	System	25 Aug 2020 00:33:03

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:32:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'f08a5224-4a59-4bea-acd3-b1410546d97c'	System	25 Aug 2020 00:33:03
User entered 'No (N)'	System	25 Aug 2020 00:33:03

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:32:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'f08a5224-4a59-4bea-acd3-b1410546d97c'	System	25 Aug 2020 00:33:03
User entered '24 Aug 2020 19:32'	System	25 Aug 2020 00:33:03

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 14:14'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 2'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:12', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '37f163e5-0eb8-4143-8f86-b58fb3ca76a2'	System	26 Aug 2020 00:02:27
User entered 'Yes (Y)'	System	26 Aug 2020 00:02:27

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '37f163e5-0eb8-4143-8f86-b58fb3ca76a2'	System	26 Aug 2020 00:02:27
User entered '96.5'	System	26 Aug 2020 00:02:27

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:20', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '37f163e5-0eb8-4143-8f86-b58fb3ca76a2'	System	26 Aug 2020 00:02:27
User entered 'No (N)'	System	26 Aug 2020 00:02:27

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '37f163e5-0eb8-4143-8f86-b58fb3ca76a2'	System	26 Aug 2020 00:02:27
User entered '25 Aug 2020 19:02'	System	26 Aug 2020 00:02:27

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 3'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:34', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '229d76b6-170f-483c-bdef-16a09d1aced8'	System	27 Aug 2020 00:39:48
User entered 'Yes (Y)'	System	27 Aug 2020 00:39:48



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '229d76b6-170f-483c-bdef-16a09d1aced8'	System	27 Aug 2020 00:39:48
User entered '93.0'	System	27 Aug 2020 00:39:48

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '229d76b6-170f-483c-bdef-16a09d1aced8'	System	27 Aug 2020 00:39:48
User entered 'No (N)'	System	27 Aug 2020 00:39:48

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:46', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '229d76b6-170f-483c-bdef-16a09d1aced8'	System	27 Aug 2020 00:39:48
User entered '26 Aug 2020 19:39'	System	27 Aug 2020 00:39:48

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 4'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:25', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '039c12f0-2a32-4e62-bea9-a6f0322d5bd2'	System	28 Aug 2020 11:40:43
User entered 'Yes (Y)'	System	28 Aug 2020 11:40:43

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:36', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '039c12f0-2a32-4e62-bea9-a6f0322d5bd2'	System	28 Aug 2020 11:40:43
User entered '95.6'	System	28 Aug 2020 11:40:43



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '039c12f0-2a32-4e62-bea9-a6f0322d5bd2'	System	28 Aug 2020 11:40:43
User entered 'No (N)'	System	28 Aug 2020 11:40:43

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '039c12f0-2a32-4e62-bea9-a6f0322d5bd2'	System	28 Aug 2020 11:40:43
User entered '28 Aug 2020 06:40'	System	28 Aug 2020 11:40:43

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 5'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:14:46', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0b56d71f-03d8-4293-9623-3445cbca7670'	System	29 Aug 2020 01:15:01
User entered 'Yes (Y)'	System	29 Aug 2020 01:15:01

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:14:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0b56d71f-03d8-4293-9623-3445cbca7670'	System	29 Aug 2020 01:15:01
User entered '95.5'	System	29 Aug 2020 01:15:01

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:14:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0b56d71f-03d8-4293-9623-3445cbca7670'	System	29 Aug 2020 01:15:01
User entered 'No (N)'	System	29 Aug 2020 01:15:01



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:14:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0b56d71f-03d8-4293-9623-3445cbca7670'	System	29 Aug 2020 01:15:01
User entered '28 Aug 2020 20:14'	System	29 Aug 2020 01:15:01

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 6'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:50:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a5706d0c-a37b-4f3b-8ca8-15047c8a9412'	System	30 Aug 2020 01:51:37
User entered 'Yes (Y)'	System	30 Aug 2020 01:51:37

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a5706d0c-a37b-4f3b-8ca8-15047c8a9412'	System	30 Aug 2020 01:51:37
User entered '93.8'	System	30 Aug 2020 01:51:37

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:29', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a5706d0c-a37b-4f3b-8ca8-15047c8a9412'	System	30 Aug 2020 01:51:37
User entered 'No (N)'	System	30 Aug 2020 01:51:37

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a5706d0c-a37b-4f3b-8ca8-15047c8a9412'	System	30 Aug 2020 01:51:37
User entered '29 Aug 2020 20:51'	System	30 Aug 2020 01:51:37



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 7'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2b24df4a-05c0-4ccd-94d9-7058b6405480'	System	31 Aug 2020 01:58:21
User entered 'Yes (Y)'	System	31 Aug 2020 01:58:21

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:11', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2b24df4a-05c0-4ccd-94d9-7058b6405480'	System	31 Aug 2020 01:58:21
User entered '94.7'	System	31 Aug 2020 01:58:21

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:13', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2b24df4a-05c0-4ccd-94d9-7058b6405480'	System	31 Aug 2020 01:58:21
User entered 'No (N)'	System	31 Aug 2020 01:58:21

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:20', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2b24df4a-05c0-4ccd-94d9-7058b6405480'	System	31 Aug 2020 01:58:21
User entered '30 Aug 2020 20:58'	System	31 Aug 2020 01:58:21

US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:24', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '30c6824c-4db2-4b65-a4b7-00f8f2f951e6'	System	24 Aug 2020 16:08:46
User entered 'None (1)'	System	24 Aug 2020 16:08:46

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:29', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '30c6824c-4db2-4b65-a4b7-00f8f2f951e6'	System	24 Aug 2020 16:08:46
User entered 'No (N)'	System	24 Aug 2020 16:08:46

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '30c6824c-4db2-4b65-a4b7-00f8f2f951e6'	System	24 Aug 2020 16:08:46
User entered 'No (N)'	System	24 Aug 2020 16:08:46

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:39', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '30c6824c-4db2-4b65-a4b7-00f8f2f951e6'	System	24 Aug 2020 16:08:46
User entered 'None (1)'	System	24 Aug 2020 16:08:46

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:44', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '30c6824c-4db2-4b65-a4b7-00f8f2f951e6'	System	24 Aug 2020 16:08:46
User entered '24 Aug 2020 11:08'	System	24 Aug 2020 16:08:46

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 10:49'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 13:19'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'aba0bdf2-a12b-4911-a4fd-f2cfa886b1d1'	System	25 Aug 2020 00:33:18
User entered 'None (1)'	System	25 Aug 2020 00:33:18

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'aba0bdf2-a12b-4911-a4fd-f2cfa886b1d1'	System	25 Aug 2020 00:33:18
User entered 'No (N)'	System	25 Aug 2020 00:33:18

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:09', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'aba0bdf2-a12b-4911-a4fd-f2cfa886b1d1'	System	25 Aug 2020 00:33:18
User entered 'No (N)'	System	25 Aug 2020 00:33:18

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:13', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'aba0bdf2-a12b-4911-a4fd-f2cfa886b1d1'	System	25 Aug 2020 00:33:18
User entered 'None (1)'	System	25 Aug 2020 00:33:18

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:16', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'aba0bdf2-a12b-4911-a4fd-f2cfa886b1d1'	System	25 Aug 2020 00:33:18
User entered '24 Aug 2020 19:33'	System	25 Aug 2020 00:33:18

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 14:14'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 2'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:27', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a9e7330a-b04a-4444-8f6f-14c1aa9f8b9a'	System	26 Aug 2020 00:02:43
User entered 'None (1)'	System	26 Aug 2020 00:02:43

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a9e7330a-b04a-4444-8f6f-14c1aa9f8b9a'	System	26 Aug 2020 00:02:43
User entered 'No (N)'	System	26 Aug 2020 00:02:43

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:33', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a9e7330a-b04a-4444-8f6f-14c1aa9f8b9a'	System	26 Aug 2020 00:02:43
User entered 'No (N)'	System	26 Aug 2020 00:02:43

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a9e7330a-b04a-4444-8f6f-14c1aa9f8b9a'	System	26 Aug 2020 00:02:43
User entered 'None (1)'	System	26 Aug 2020 00:02:43

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a9e7330a-b04a-4444-8f6f-14c1aa9f8b9a'	System	26 Aug 2020 00:02:43
User entered '25 Aug 2020 19:02'	System	26 Aug 2020 00:02:43

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 3'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:50', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e805a601-5ba9-4ee9-ac2e-11c239df38d5'	System	27 Aug 2020 00:40:06
User entered 'None (1)'	System	27 Aug 2020 00:40:06

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e805a601-5ba9-4ee9-ac2e-11c239df38d5'	System	27 Aug 2020 00:40:06
User entered 'No (N)'	System	27 Aug 2020 00:40:06

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:56', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e805a601-5ba9-4ee9-ac2e-11c239df38d5'	System	27 Aug 2020 00:40:06
User entered 'No (N)'	System	27 Aug 2020 00:40:06

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:39:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e805a601-5ba9-4ee9-ac2e-11c239df38d5'	System	27 Aug 2020 00:40:06
User entered 'None (1)'	System	27 Aug 2020 00:40:06

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:01', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e805a601-5ba9-4ee9-ac2e-11c239df38d5'	System	27 Aug 2020 00:40:06
User entered '26 Aug 2020 19:40'	System	27 Aug 2020 00:40:06

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 4'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:56', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e60933b4-3747-4750-88fb-a30056fdd933'	System	28 Aug 2020 11:41:10
User entered 'None (1)'	System	28 Aug 2020 11:41:10

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:40:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e60933b4-3747-4750-88fb-a30056fdd933'	System	28 Aug 2020 11:41:10
User entered 'No (N)'	System	28 Aug 2020 11:41:10

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:02', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e60933b4-3747-4750-88fb-a30056fdd933'	System	28 Aug 2020 11:41:10
User entered 'No (N)'	System	28 Aug 2020 11:41:10

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:05', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e60933b4-3747-4750-88fb-a30056fdd933'	System	28 Aug 2020 11:41:10
User entered 'None (1)'	System	28 Aug 2020 11:41:10

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:08', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e60933b4-3747-4750-88fb-a30056fdd933'	System	28 Aug 2020 11:41:10
User entered '28 Aug 2020 06:41'	System	28 Aug 2020 11:41:10

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 5'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:01', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd66dd991-48e9-4bc6-8bd8-fb767d75346b'	System	29 Aug 2020 01:15:16
User entered 'None (1)'	System	29 Aug 2020 01:15:16

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd66dd991-48e9-4bc6-8bd8-fb767d75346b'	System	29 Aug 2020 01:15:16
User entered 'No (N)'	System	29 Aug 2020 01:15:16

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd66dd991-48e9-4bc6-8bd8-fb767d75346b'	System	29 Aug 2020 01:15:16
User entered 'No (N)'	System	29 Aug 2020 01:15:16

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:09', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd66dd991-48e9-4bc6-8bd8-fb767d75346b'	System	29 Aug 2020 01:15:16
User entered 'None (1)'	System	29 Aug 2020 01:15:16

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:12', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd66dd991-48e9-4bc6-8bd8-fb767d75346b'	System	29 Aug 2020 01:15:16
User entered '28 Aug 2020 20:15'	System	29 Aug 2020 01:15:16

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 6'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:36', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'ad6eac16-1e5d-4470-9622-018f3f804a7f'	System	30 Aug 2020 01:51:48
User entered 'None (1)'	System	30 Aug 2020 01:51:48

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'ad6eac16-1e5d-4470-9622-018f3f804a7f'	System	30 Aug 2020 01:51:48
User entered 'No (N)'	System	30 Aug 2020 01:51:48

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:40', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'ad6eac16-1e5d-4470-9622-018f3f804a7f'	System	30 Aug 2020 01:51:48
User entered 'No (N)'	System	30 Aug 2020 01:51:48

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'ad6eac16-1e5d-4470-9622-018f3f804a7f'	System	30 Aug 2020 01:51:48
User entered 'None (1)'	System	30 Aug 2020 01:51:48

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:45', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'ad6eac16-1e5d-4470-9622-018f3f804a7f'	System	30 Aug 2020 01:51:48
User entered '29 Aug 2020 20:51'	System	30 Aug 2020 01:51:48

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 7'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e957a91b-8a9a-401f-ad76-4c07b9e26567'	System	31 Aug 2020 01:58:37
User entered 'None (1)'	System	31 Aug 2020 01:58:37

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e957a91b-8a9a-401f-ad76-4c07b9e26567'	System	31 Aug 2020 01:58:37
User entered 'No (N)'	System	31 Aug 2020 01:58:37

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:28', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e957a91b-8a9a-401f-ad76-4c07b9e26567'	System	31 Aug 2020 01:58:37
User entered 'No (N)'	System	31 Aug 2020 01:58:37

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e957a91b-8a9a-401f-ad76-4c07b9e26567'	System	31 Aug 2020 01:58:37
User entered 'None (1)'	System	31 Aug 2020 01:58:37

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e957a91b-8a9a-401f-ad76-4c07b9e26567'	System	31 Aug 2020 01:58:37
User entered '30 Aug 2020 20:58'	System	31 Aug 2020 01:58:37

US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:08:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:09:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:09:01', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:09:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'None (0)'	System	24 Aug 2020 16:09:17



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:09:09', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered 'No (N)'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T11:09:14', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '002ff586-a10f-4e63-8948-e0890bfc97f6'	System	24 Aug 2020 16:09:17
User entered '24 Aug 2020 11:09'	System	24 Aug 2020 16:09:17

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 10:49'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 13:19'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:19', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:25', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:28', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:29', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'None (0)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:35', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered 'No (N)'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-24T19:33:37', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '1236a0b9-af80-48ce-b85a-439de3a0f68d'	System	25 Aug 2020 00:33:41
User entered '24 Aug 2020 19:33'	System	25 Aug 2020 00:33:41

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Aug 2020 14:14'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 2'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:44', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:46', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:48', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:49', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:52', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'None (0)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:02:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered 'No (N)'	System	26 Aug 2020 00:03:06

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-25T19:03:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5112c33b-82a8-47fc-a782-6fdfedbc67d0'	System	26 Aug 2020 00:03:06
User entered '25 Aug 2020 19:03'	System	26 Aug 2020 00:03:06



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 3'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:09', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:10', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:12', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'None (0)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:14', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered 'No (N)'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-26T19:40:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af0b7b0f-f239-4770-89af-d53e240f7a44'	System	27 Aug 2020 00:40:20
User entered '26 Aug 2020 19:40'	System	27 Aug 2020 00:40:20

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 4'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:11', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:13', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:15', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:16', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:19', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:22', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'None (0)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:25', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered 'No (N)'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T06:41:28', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0d3c93e0-e68d-4bef-8919-f6089cd511ef'	System	28 Aug 2020 11:41:29
User entered '28 Aug 2020 06:41'	System	28 Aug 2020 11:41:29

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 5'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:15', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:18', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:20', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'None (0)'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:27', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered 'No (N)'	System	29 Aug 2020 01:15:32



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-28T20:15:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '09d9f535-fe59-4ca9-ae2f-9b3ccc77d392'	System	29 Aug 2020 01:15:32
User entered '28 Aug 2020 20:15'	System	29 Aug 2020 01:15:32

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 6'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:48', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:50', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:57', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:51:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'None (0)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:52:02', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered 'No (N)'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-29T20:52:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '64f3173c-0a96-4b57-94de-1433717ea29c'	System	30 Aug 2020 01:52:08
User entered '29 Aug 2020 20:52'	System	30 Aug 2020 01:52:08

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 7'	System	24 Aug 2020 15:41:33

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:35', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:37', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:39', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:45', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'None (0)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:48', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered 'No (N)'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-08-30T20:58:50', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7065ff0d-ce6b-4b0f-8cbd-c72b271dd896'	System	31 Aug 2020 01:58:54
User entered '30 Aug 2020 20:58'	System	31 Aug 2020 01:58:54

US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:41:33



US3312225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:55:26

US3312225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '31 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:55:26

US3312225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:55:26

US3312225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4)	01 Sep 2020 15:55:26
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:55:29

US3312225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'I'	System	01 Sep 2020 15:55:29

US3312225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:18



US3312225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered '7 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:18

US3312225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:18

US3312225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered empty.	(b) (4)	15 Sep 2020 00:32:18
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:21

US3312225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:58
User entered 'I'	System	15 Sep 2020 00:32:21

US3312225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 00:32:29
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:29

US3312225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:32:29



US3312225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered empty.	(b) (4)	15 Sep 2020 00:32:29
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 00:32:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User entered 'I'	System	15 Sep 2020 00:32:37

US3312225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
Query 'Per CDM: Please complete remaining V2 forms. ' canceled (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 01:55:51
User opened query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:42:12
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Sep 2020 14:50:01
	(b) (4)	

US3312225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:01

US3312225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:01

US3312225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'VISIT2'	System	21 Sep 2020 14:50:01

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	19 Oct 2020 02:38:21
	(b) (4)	



US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '08:29'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '21 Sep 2020 08:29'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '98.2' F	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21



US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'bpm'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'breaths/min'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '118'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '84'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21



US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '10:17'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '21 Sep 2020 10:17'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '98.2' F	(b) (4)	19 Oct 2020 02:38:21
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '74'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21



US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'bpm'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'breaths/min'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '133'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '88'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	19 Oct 2020 02:38:21

US3312225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:38:27



US3312225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:27

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User closed query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 07:56:12
Query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:36
User opened query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:56:00
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:46'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '21 Sep 2020 09:46'	System	21 Sep 2020 14:50:23



US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'ONCE'	System	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:04:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:50:23

US3312225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:38:45

US3312225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:38:45

US3312225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:14'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:38:45

US3312225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '21 Sep 2020 09:14'	System	19 Oct 2020 02:38:45

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09



US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '09:05'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:04:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '21 Sep 2020 09:05'	System	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:39:09

US3312225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:04:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered empty.	System	19 Oct 2020 02:39:09



US3312225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 14:50:30

US3312225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '1'	System	21 Sep 2020 14:50:30

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2266b0cd-8214-40b6-ac46-d6558a4a1224'	System	21 Sep 2020 15:21:27
User entered 'Yes (Y)'	System	21 Sep 2020 15:21:27

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:12', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2266b0cd-8214-40b6-ac46-d6558a4a1224' User entered '98.2'	System	21 Sep 2020 15:21:27

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2266b0cd-8214-40b6-ac46-d6558a4a1224'	System	21 Sep 2020 15:21:27
User entered 'No (N)'	System	21 Sep 2020 15:21:27

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2266b0cd-8214-40b6-ac46-d6558a4a1224'	System	21 Sep 2020 15:21:27
User entered '21 Sep 2020 10:21'	System	21 Sep 2020 15:21:27

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 10:06'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:15', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04dcd47a-bad7-46e7-a6be-5910f08cba86'	System	21 Sep 2020 23:35:28
User entered 'Yes (Y)'	System	21 Sep 2020 23:35:28

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:20', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04dcd47a-bad7-46e7-a6be-5910f08cba86'	System	21 Sep 2020 23:35:28
User entered '94.7'	System	21 Sep 2020 23:35:28

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04dcd47a-bad7-46e7-a6be-5910f08cba86'	System	21 Sep 2020 23:35:28
User entered 'No (N)'	System	21 Sep 2020 23:35:28

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04dcd47a-bad7-46e7-a6be-5910f08cba86'	System	21 Sep 2020 23:35:28
User entered '21 Sep 2020 18:35'	System	21 Sep 2020 23:35:28

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 13:31'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 2'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:39:54', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '83789b99-a90f-4318-b452-76389e5f78ac'	System	23 Sep 2020 10:40:09
User entered 'Yes (Y)'	System	23 Sep 2020 10:40:09

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:39:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '83789b99-a90f-4318-b452-76389e5f78ac'	System	23 Sep 2020 10:40:09
User entered '98.1'	System	23 Sep 2020 10:40:09

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '83789b99-a90f-4318-b452-76389e5f78ac'	System	23 Sep 2020 10:40:09
User entered 'No (N)'	System	23 Sep 2020 10:40:09

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '83789b99-a90f-4318-b452-76389e5f78ac'	System	23 Sep 2020 10:40:09
User entered '23 Sep 2020 05:40'	System	23 Sep 2020 10:40:09

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 3'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:41:52', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '18afc70f-0941-4edf-8bdf-eb9ddf46fbcc'	System	24 Sep 2020 12:42:12
User entered 'Yes (Y)'	System	24 Sep 2020 12:42:12

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:41:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '18afc70f-0941-4edf-8bdf-eb9ddf46fbcc'	System	24 Sep 2020 12:42:12
User entered '93.7'	System	24 Sep 2020 12:42:12

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '18afc70f-0941-4edf-8bdf-eb9ddf46fbcc'	System	24 Sep 2020 12:42:12
User entered 'No (N)'	System	24 Sep 2020 12:42:12

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '18afc70f-0941-4edf-8bdf-eb9ddf46fbcc'	System	24 Sep 2020 12:42:12
User entered '24 Sep 2020 07:42'	System	24 Sep 2020 12:42:12

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 4'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '27ac2cb3-3d19-4a70-b0fb-b522f6423ebf'	System	25 Sep 2020 14:40:41
User entered 'Yes (Y)'	System	25 Sep 2020 14:40:41



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '27ac2cb3-3d19-4a70-b0fb-b522f6423ebf'	System	25 Sep 2020 14:40:41
User entered '96.6'	System	25 Sep 2020 14:40:41

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:34', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '27ac2cb3-3d19-4a70-b0fb-b522f6423ebf'	System	25 Sep 2020 14:40:41
User entered 'No (N)'	System	25 Sep 2020 14:40:41

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:37', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '27ac2cb3-3d19-4a70-b0fb-b522f6423ebf'	System	25 Sep 2020 14:40:41
User entered '25 Sep 2020 09:40'	System	25 Sep 2020 14:40:41

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 5'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 6'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:24:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e3b76dc6-047b-470c-97df-185a2ac41af3'	System	27 Sep 2020 12:24:55
User entered 'Yes (Y)'	System	27 Sep 2020 12:24:55



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:24:48', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e3b76dc6-047b-470c-97df-185a2ac41af3'	System	27 Sep 2020 12:24:55
User entered '95.7'	System	27 Sep 2020 12:24:55

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:24:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e3b76dc6-047b-470c-97df-185a2ac41af3'	System	27 Sep 2020 12:24:55
User entered 'No (N)'	System	27 Sep 2020 12:24:55

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:24:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e3b76dc6-047b-470c-97df-185a2ac41af3'	System	27 Sep 2020 12:24:55
User entered '27 Sep 2020 07:24'	System	27 Sep 2020 12:24:55

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 7'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:28', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2c03c1a7-52a0-4b26-bf57-2ec46956775d'	System	21 Sep 2020 15:21:51
User entered 'None (1)'	System	21 Sep 2020 15:21:51



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:37', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2c03c1a7-52a0-4b26-bf57-2ec46956775d'	System	21 Sep 2020 15:21:51
User entered 'No (N)'	System	21 Sep 2020 15:21:51

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:40', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2c03c1a7-52a0-4b26-bf57-2ec46956775d'	System	21 Sep 2020 15:21:51
User entered 'No (N)'	System	21 Sep 2020 15:21:51

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2c03c1a7-52a0-4b26-bf57-2ec46956775d'	System	21 Sep 2020 15:21:51
User entered 'None (1)'	System	21 Sep 2020 15:21:51

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:46', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2c03c1a7-52a0-4b26-bf57-2ec46956775d'	System	21 Sep 2020 15:21:51
User entered '21 Sep 2020 10:21'	System	21 Sep 2020 15:21:51

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 10:06'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '8f362b02-316a-403a-b4a8-8b3fea1d48da'	System	21 Sep 2020 23:35:43
User entered 'None (1)'	System	21 Sep 2020 23:35:43



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '8f362b02-316a-403a-b4a8-8b3fea1d48da'	System	21 Sep 2020 23:35:43
User entered 'No (N)'	System	21 Sep 2020 23:35:43

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:35', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '8f362b02-316a-403a-b4a8-8b3fea1d48da'	System	21 Sep 2020 23:35:43
User entered 'No (N)'	System	21 Sep 2020 23:35:43

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:37', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '8f362b02-316a-403a-b4a8-8b3fea1d48da'	System	21 Sep 2020 23:35:43
User entered 'None (1)'	System	21 Sep 2020 23:35:43

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:40', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '8f362b02-316a-403a-b4a8-8b3fea1d48da'	System	21 Sep 2020 23:35:43
User entered '21 Sep 2020 18:35'	System	21 Sep 2020 23:35:43

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 13:31'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 2'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:11', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '24418d59-f1d4-4a90-945f-8ec72acc92ff'	System	23 Sep 2020 10:40:25
User entered 'None (1)'	System	23 Sep 2020 10:40:25



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:14', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '24418d59-f1d4-4a90-945f-8ec72acc92ff'	System	23 Sep 2020 10:40:25
User entered 'No (N)'	System	23 Sep 2020 10:40:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '24418d59-f1d4-4a90-945f-8ec72acc92ff'	System	23 Sep 2020 10:40:25
User entered 'No (N)'	System	23 Sep 2020 10:40:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:19', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '24418d59-f1d4-4a90-945f-8ec72acc92ff'	System	23 Sep 2020 10:40:25
User entered 'None (1)'	System	23 Sep 2020 10:40:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:22', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '24418d59-f1d4-4a90-945f-8ec72acc92ff'	System	23 Sep 2020 10:40:25
User entered '23 Sep 2020 05:40'	System	23 Sep 2020 10:40:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 3'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:12', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '65a825e3-ffe7-431a-8367-5b2c245a3492'	System	24 Sep 2020 12:42:24
User entered 'None (1)'	System	24 Sep 2020 12:42:24



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:15', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '65a825e3-ffe7-431a-8367-5b2c245a3492'	System	24 Sep 2020 12:42:24
User entered 'No (N)'	System	24 Sep 2020 12:42:24

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '65a825e3-ffe7-431a-8367-5b2c245a3492'	System	24 Sep 2020 12:42:24
User entered 'No (N)'	System	24 Sep 2020 12:42:24

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:20', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '65a825e3-ffe7-431a-8367-5b2c245a3492'	System	24 Sep 2020 12:42:24
User entered 'None (1)'	System	24 Sep 2020 12:42:24

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:22', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '65a825e3-ffe7-431a-8367-5b2c245a3492'	System	24 Sep 2020 12:42:24
User entered '24 Sep 2020 07:42'	System	24 Sep 2020 12:42:24

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 4'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:40', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '3d689406-6dbc-4617-b8a6-86e52ee62078'	System	25 Sep 2020 14:40:53
User entered 'None (1)'	System	25 Sep 2020 14:40:53



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '3d689406-6dbc-4617-b8a6-86e52ee62078'	System	25 Sep 2020 14:40:53
User entered 'No (N)'	System	25 Sep 2020 14:40:53

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:45', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '3d689406-6dbc-4617-b8a6-86e52ee62078'	System	25 Sep 2020 14:40:53
User entered 'No (N)'	System	25 Sep 2020 14:40:53

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:47', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '3d689406-6dbc-4617-b8a6-86e52ee62078'	System	25 Sep 2020 14:40:53
User entered 'None (1)'	System	25 Sep 2020 14:40:53

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:49', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '3d689406-6dbc-4617-b8a6-86e52ee62078'	System	25 Sep 2020 14:40:53
User entered '25 Sep 2020 09:40'	System	25 Sep 2020 14:40:53

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 5'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

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)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 6'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:24:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7bd5a5ab-ee85-4cad-9c92-1f1f1a54ba79'	System	27 Sep 2020 12:25:09
User entered 'None (1)'	System	27 Sep 2020 12:25:09

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7bd5a5ab-ee85-4cad-9c92-1f1f1a54ba79'	System	27 Sep 2020 12:25:09
User entered 'No (N)'	System	27 Sep 2020 12:25:09

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:02', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7bd5a5ab-ee85-4cad-9c92-1f1f1a54ba79'	System	27 Sep 2020 12:25:09
User entered 'No (N)'	System	27 Sep 2020 12:25:09

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7bd5a5ab-ee85-4cad-9c92-1f1f1a54ba79'	System	27 Sep 2020 12:25:09
User entered 'None (1)'	System	27 Sep 2020 12:25:09

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:07', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '7bd5a5ab-ee85-4cad-9c92-1f1f1a54ba79'	System	27 Sep 2020 12:25:09
User entered '27 Sep 2020 07:25'	System	27 Sep 2020 12:25:09

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 7'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

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)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:21:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:22:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:22:01', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'None (0)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:22:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered 'No (N)'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T10:22:08', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c201af67-5e6b-4cd7-95dd-7adecdd346a5'	System	21 Sep 2020 15:22:13
User entered '21 Sep 2020 10:22'	System	21 Sep 2020 15:22:13

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 10:06'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:44', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:45', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:47', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:49', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'None (0)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:56', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered 'No (N)'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-21T18:35:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '19ea4634-d22e-402b-8e5e-afafc0114e38'	System	21 Sep 2020 23:36:01
User entered '21 Sep 2020 18:35'	System	21 Sep 2020 23:36:01

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '21 Sep 2020 13:31'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 2'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:28', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:31', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:36', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'None (0)'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:42', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered 'No (N)'	System	23 Sep 2020 10:40:49



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-23T05:40:44', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6d19a840-0c76-4000-96ca-bbfd3e55a208'	System	23 Sep 2020 10:40:49
User entered '23 Sep 2020 05:40'	System	23 Sep 2020 10:40:49

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 3'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:25', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:27', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:29', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:32', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:33', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'None (0)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered 'No (N)'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-24T07:42:41', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '0f6307ea-5ba9-4358-9fb8-685a79470d37'	System	24 Sep 2020 12:42:58
User entered '24 Sep 2020 07:42'	System	24 Sep 2020 12:42:58

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 4'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:55', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:56', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:40:59', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:41:01', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'None (0)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:41:04', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered 'No (N)'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-25T09:41:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '94e9238a-8dcf-4e4a-8554-fd48db8731bd'	System	25 Sep 2020 14:41:09
User entered '25 Sep 2020 09:41'	System	25 Sep 2020 14:41:09

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 5'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 6'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:10', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:11', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:14', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:19', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'None (0)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:23', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered 'No (N)'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-09-27T07:25:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a8dee729-c448-4186-acb3-548dc9091f0f'	System	27 Sep 2020 12:25:29
User entered '27 Sep 2020 07:25'	System	27 Sep 2020 12:25:29

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	21 Sep 2020 14:50:23
User entered 'Day 7'	System	21 Sep 2020 14:50:23



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25



US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:23

US3312225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:04:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:23

US3312225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 02:40:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:04

US3312225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:40:04

US3312225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered empty.	(b) (4)	19 Oct 2020 02:40:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 02:40:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'I'	System	19 Oct 2020 02:40:08



US3312225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 02:40:22
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered '05 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:22

US3312225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:22

US3312225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered empty.	(b) (4)	19 Oct 2020 02:40:22
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:25

US3312225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'I'	System	19 Oct 2020 02:40:25

US3312225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 02:40:42
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:42



US3312225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:42

US3312225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:40:42

US3312225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:55
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 02:40:46
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'I'	System	19 Oct 2020 02:40:46

US3312225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:24

US3312225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:24

US3312225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:24

US3312225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'VISIT3'	System	20 Oct 2020 19:14:24



US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '08:17'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '19 Oct 2020 08:17'	System	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '74'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54



US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'bpm'	System	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '14'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'breaths/min'	System	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '126'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '85'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'mmHg'	System	20 Oct 2020 19:14:54

US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04



US3312225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04

US3312225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:57

US3312225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:14:57

US3312225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:15:08

US3312225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:15:08

US3312225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered '08:29'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:15:08

US3312225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '19 Oct 2020 08:29'	System	20 Oct 2020 19:15:08

US3312225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:20:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:15:12



US3312225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered '1'	System	20 Oct 2020 19:15:12

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 64'	System	24 Aug 2020 15:41:33

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-10-26T14:50:44', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2a05e7bb-34a6-43ff-b183-a2b420babc0a'	System	26 Oct 2020 19:50:56
User entered 'No (N)'	System	26 Oct 2020 19:50:56

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-10-26T14:50:49', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2a05e7bb-34a6-43ff-b183-a2b420bab0a'	System	26 Oct 2020 19:50:56
User entered 'No (N)'	System	26 Oct 2020 19:50:56

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-10-26T14:50:52', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '2a05e7bb-34a6-43ff-b183-a2b420babc0a' User entered '26 Oct 2020 14:50:52'	System	26 Oct 2020 19:50:56
	System	26 Oct 2020 19:50:56

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 15:41:33

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 71'	System	24 Aug 2020 15:41:33



US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-02T18:42:18', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e032d8e8-e48d-412e-ac6a-97adcf049c42'	System	03 Nov 2020 00:42:35
User entered 'No (N)'	System	03 Nov 2020 00:42:35

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-02T18:42:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e032d8e8-e48d-412e-ac6a-97adcf049c42'	System	03 Nov 2020 00:42:35
User entered 'No (N)'	System	03 Nov 2020 00:42:35

**US3312225**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-02T18:42:31', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'e032d8e8-e48d-412e-ac6a-97adcf049c42'	System	03 Nov 2020 00:42:35
User entered '02 Nov 2020 18:42:31'	System	03 Nov 2020 00:42:35

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 15:41:33

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 15:41:33

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered 'Day 78'	System	24 Aug 2020 15:41:33

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:31:34', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'Yes (Y)'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:31:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'Yes (Y)'	System	09 Nov 2020 15:33:36



US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Please 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)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:31:43', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

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)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:31:49', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'Yes (Y)'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36



US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4' User entered '0'	System	09 Nov 2020 15:33:36
	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36



US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '0'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '1'	System	09 Nov 2020 15:33:36

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Please 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)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[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)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:17', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'Yes (Y)'	System	09 Nov 2020 15:33:36

US3312225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Please 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)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-11-09T09:33:24', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'a4001b8c-fe8f-44b2-b34c-0c1c2b1891e4'	System	09 Nov 2020 15:33:36
User entered '09 Nov 2020 09:33:24'	System	09 Nov 2020 15:33:36

US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 15:41:33



US3312225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:25
Data entry locked.	System	24 Aug 2020 15:41:33
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 15:41:33

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-09T19:13:21', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9006a0fd-953e-4c60-8b5c-6fb61d5a022f'	System	10 Dec 2020 01:13:34
User entered 'No (N)'	System	10 Dec 2020 01:13:34

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-09T19:13:24', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9006a0fd-953e-4c60-8b5c-6fb61d5a022f'	System	10 Dec 2020 01:13:34
User entered 'No (N)'	System	10 Dec 2020 01:13:34

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-09T19:13:27', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9006a0fd-953e-4c60-8b5c-6fb61d5a022f' User entered '09 Dec 2020 19:13:27'	System	10 Dec 2020 01:13:34

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-17T10:23:26', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '36ab2ed6-649b-4898-a5c7-a8c6b9783d4b'	System	17 Dec 2020 16:23:36
User entered 'No (N)'	System	17 Dec 2020 16:23:36

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-17T10:23:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '36ab2ed6-649b-4898-a5c7-a8c6b9783d4b'	System	17 Dec 2020 16:23:36
User entered 'No (N)'	System	17 Dec 2020 16:23:36

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-17T10:23:33', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '36ab2ed6-649b-4898-a5c7-a8c6b9783d4b'	System	17 Dec 2020 16:23:36
User entered '17 Dec 2020 10:23:33'	System	17 Dec 2020 16:23:36

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-23T16:43:51', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '954f005b-6d8a-40a3-af7e-3abee7d5f65d'	System	23 Dec 2020 22:43:59
User entered 'No (N)'	System	23 Dec 2020 22:43:59



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-23T16:43:53', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '954f005b-6d8a-40a3-af7e-3abee7d5f65d'	System	23 Dec 2020 22:43:59
User entered 'No (N)'	System	23 Dec 2020 22:43:59

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-23T16:43:56', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '954f005b-6d8a-40a3-af7e-3abee7d5f65d'	System	23 Dec 2020 22:43:59
User entered '23 Dec 2020 16:43:56'	System	23 Dec 2020 22:43:59

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-30T19:56:03', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '894261c7-5784-4d4d-965d-3980d7424e72'	System	31 Dec 2020 01:56:14
User entered 'No (N)'	System	31 Dec 2020 01:56:14

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-30T19:56:06', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '894261c7-5784-4d4d-965d-3980d7424e72'	System	31 Dec 2020 01:56:14
User entered 'No (N)'	System	31 Dec 2020 01:56:14

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2020-12-30T19:56:11', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '894261c7-5784-4d4d-965d-3980d7424e72'	System	31 Dec 2020 01:56:14
User entered '30 Dec 2020 19:56:11'	System	31 Dec 2020 01:56:14



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-08T08:25:58', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af2aae33-0b7c-4aa3-9aea-c7c33c9b279e'	System	08 Jan 2021 14:26:11
User entered 'No (N)'	System	08 Jan 2021 14:26:11

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-08T08:26:02', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af2aae33-0b7c-4aa3-9aea-c7c33c9b279e'	System	08 Jan 2021 14:26:11
User entered 'No (N)'	System	08 Jan 2021 14:26:11

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-08T08:26:05', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'af2aae33-0b7c-4aa3-9aea-c7c33c9b279e'	System	08 Jan 2021 14:26:11
User entered '08 Jan 2021 08:26:05'	System	08 Jan 2021 14:26:11

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-15T15:59:46', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'b80076e4-4403-41be-891f-9c9f59217011'	System	15 Jan 2021 22:00:14
User entered 'No (N)'	System	15 Jan 2021 22:00:14

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-15T15:59:48', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'b80076e4-4403-41be-891f-9c9f59217011'	System	15 Jan 2021 22:00:14
User entered 'No (N)'	System	15 Jan 2021 22:00:14

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-15T16:00:10', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'b80076e4-4403-41be-891f-9c9f59217011'	System	15 Jan 2021 22:00:14
User entered '15 Jan 2021 16:00:10'	System	15 Jan 2021 22:00:14

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:35:53

US3312225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-20T15:35:16', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6169b8bb-9f1e-4156-bad9-cd9af575e76a'	System	21 Jan 2021 18:57:45
User entered 'No (N)'	System	21 Jan 2021 18:57:45



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-21T12:57:38', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6169b8bb-9f1e-4156-bad9-cd9af575e76a'	System	21 Jan 2021 18:57:45
User entered 'No (N)'	System	21 Jan 2021 18:57:45

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-21T12:57:42', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '6169b8bb-9f1e-4156-bad9-cd9af575e76a' User entered '21 Jan 2021 12:57:42'	System	21 Jan 2021 18:57:45

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-28T08:29:27', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5243a460-b4a9-4af5-9582-ebc5cc66f08f'	System	28 Jan 2021 14:29:36
User entered 'No (N)'	System	28 Jan 2021 14:29:36

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-28T08:29:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5243a460-b4a9-4af5-9582-ebc5cc66f08f'	System	28 Jan 2021 14:29:36
User entered 'No (N)'	System	28 Jan 2021 14:29:36

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-01-28T08:29:33', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '5243a460-b4a9-4af5-9582-ebc5cc66f08f' User entered '28 Jan 2021 08:29:33'	System	28 Jan 2021 14:29:36
	System	28 Jan 2021 14:29:36



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-11T16:21:30', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'dd8fe972-e9f1-417e-9096-6d396e94bf07'	System	11 Feb 2021 22:21:40
User entered 'No (N)'	System	11 Feb 2021 22:21:40

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-11T16:21:33', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'dd8fe972-e9f1-417e-9096-6d396e94bf07'	System	11 Feb 2021 22:21:40
User entered 'No (N)'	System	11 Feb 2021 22:21:40



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-11T16:21:36', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'dd8fe972-e9f1-417e-9096-6d396e94bf07'	System	11 Feb 2021 22:21:40
User entered '11 Feb 2021 16:21:36'	System	11 Feb 2021 22:21:40

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-26T18:10:55-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c6fc6301-50fb-4267-841f-114c3544ce0b' User entered 'No (N)'	System	27 Feb 2021 00:15:00
	System	27 Feb 2021 00:15:00



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-26T18:10:58-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c6fc6301-50fb-4267-841f-114c3544ce0b' User entered 'No (N)'	System	27 Feb 2021 00:15:00
	System	27 Feb 2021 00:15:00

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-02-26T18:11:02-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'c6fc6301-50fb-4267-841f-114c3544ce0b'	System	27 Feb 2021 00:15:00
User entered '26 Feb 2021 18:11:02'	System	27 Feb 2021 00:15:00

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-04T10:34:42-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '313a139d-ea06-4ff0-93a1-9ba8e31ff8b8'	System	04 Mar 2021 16:34:52
User entered 'No (N)'	System	04 Mar 2021 16:34:52

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-04T10:34:45-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '313a139d-ea06-4ff0-93a1-9ba8e31ff8b8'	System	04 Mar 2021 16:34:52
User entered 'No (N)'	System	04 Mar 2021 16:34:52

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-04T10:34:47-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '313a139d-ea06-4ff0-93a1-9ba8e31ff8b8' User entered '04 Mar 2021 10:34:47'	System	04 Mar 2021 16:34:52
	System	04 Mar 2021 16:34:52



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-11T10:32:22-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9ef38708-b016-4c4c-9af9-4b7440fbe033'	System	11 Mar 2021 16:32:31
User entered 'No (N)'	System	11 Mar 2021 16:32:31

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-11T10:32:25-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9ef38708-b016-4c4c-9af9-4b7440fbe033'	System	11 Mar 2021 16:32:31
User entered 'No (N)'	System	11 Mar 2021 16:32:31

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-11T10:32:27-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '9ef38708-b016-4c4c-9af9-4b7440fbe033' User entered '11 Mar 2021 10:32:27'	System	11 Mar 2021 16:32:31
	System	11 Mar 2021 16:32:31

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-18T22:15:36-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '81397a83-6a14-41d1-894f-4539f29ede20'	System	19 Mar 2021 02:15:49
User entered 'No (N)'	System	19 Mar 2021 02:15:49

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-18T22:15:39-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '81397a83-6a14-41d1-894f-4539f29ede20'	System	19 Mar 2021 02:15:49
User entered 'No (N)'	System	19 Mar 2021 02:15:49

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-18T22:15:44-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '81397a83-6a14-41d1-894f-4539f29ede20'	System	19 Mar 2021 02:15:49
User entered '18 Mar 2021 22:15:44'	System	19 Mar 2021 02:15:49

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-24T16:50:03-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04b350fb-9612-4e2e-a34d-78e8be4206a9' User entered 'No (N)'	System	24 Mar 2021 21:50:12
	System	24 Mar 2021 21:50:12



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-24T16:50:06-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04b350fb-9612-4e2e-a34d-78e8be4206a9'	System	24 Mar 2021 21:50:12
User entered 'No (N)'	System	24 Mar 2021 21:50:12

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-24T16:50:08-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '04b350fb-9612-4e2e-a34d-78e8be4206a9' User entered '24 Mar 2021 16:50:08'	System	24 Mar 2021 21:50:12
	System	24 Mar 2021 21:50:12

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-02T14:12:56-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '744ab3fd-5b50-41ae-9d14-0afcba78d011' User entered 'No (N)'	System	02 Apr 2021 19:13:06
	System	02 Apr 2021 19:13:06

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-02T14:12:59-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '744ab3fd-5b50-41ae-9d14-0afcba78d011' User entered 'No (N)'	System	02 Apr 2021 19:13:06

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-02T14:13:03-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '744ab3fd-5b50-41ae-9d14-0afcba78d011'	System	02 Apr 2021 19:13:06
User entered '02 Apr 2021 14:13:03'	System	02 Apr 2021 19:13:06



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-08T14:35:20-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '73e7d9d4-0ffb-421a-8bca-24c1f042e085'	System	09 Apr 2021 19:01:27
User entered 'No (N)'	System	09 Apr 2021 19:01:27

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-09T15:01:14-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '73e7d9d4-0ffb-421a-8bca-24c1f042e085'	System	09 Apr 2021 19:01:27
User entered 'No (N)'	System	09 Apr 2021 19:01:27

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-09T15:01:16-04:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '73e7d9d4-0ffb-421a-8bca-24c1f042e085'	System	09 Apr 2021 19:01:27
User entered '09 Apr 2021 15:01:16'	System	09 Apr 2021 19:01:27

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-14T15:15:46-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'be436dc9-b443-4a7d-92b3-8fd0c4f84462'	System	14 Apr 2021 20:15:59
User entered 'No (N)'	System	14 Apr 2021 20:15:59

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-14T15:15:49-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'be436dc9-b443-4a7d-92b3-8fd0c4f84462'	System	14 Apr 2021 20:15:59
User entered 'No (N)'	System	14 Apr 2021 20:15:59

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-14T15:15:52-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'be436dc9-b443-4a7d-92b3-8fd0c4f84462' User entered '14 Apr 2021 15:15:52'	System	14 Apr 2021 20:15:59
	System	14 Apr 2021 20:15:59

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-23T08:02:02-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd0231455-2e56-44a6-8ea0-5409c2190061'	System	23 Apr 2021 13:02:13
User entered 'No (N)'	System	23 Apr 2021 13:02:13



US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-23T08:02:05-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd0231455-2e56-44a6-8ea0-5409c2190061'	System	23 Apr 2021 13:02:13
User entered 'No (N)'	System	23 Apr 2021 13:02:13

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-23T08:02:08-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'd0231455-2e56-44a6-8ea0-5409c2190061'	System	23 Apr 2021 13:02:13
User entered '23 Apr 2021 08:02:08'	System	23 Apr 2021 13:02:13

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-29T11:41:50-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'fc23adc9-2be0-4348-87a5-fe58e07aca39'	System	29 Apr 2021 16:41:58
User entered 'No (N)'	System	29 Apr 2021 16:41:58

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-29T11:41:53-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'fc23adc9-2be0-4348-87a5-fe58e07aca39'	System	29 Apr 2021 16:41:58
User entered 'No (N)'	System	29 Apr 2021 16:41:58

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-04-29T11:41:55-05:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: 'fc23adc9-2be0-4348-87a5-fe58e07aca39'	System	29 Apr 2021 16:41:58
User entered '29 Apr 2021 11:41:55'	System	29 Apr 2021 16:41:58



US3312225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:35:53

US3312225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:35:53

US3312225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:04:11

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:35:53



**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:35:53

**US3312225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:04:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:53
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:35:53

US3312225

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:04:11**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:17:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-04T10:34:33-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '290cb4ee-aeec-4849-9336-8ffac68ead05'	System	04 Mar 2021 16:34:40
User entered 'No (N)'	System	04 Mar 2021 16:34:40

US3312225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:04:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:17:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2080b0e2080e0601)', Time: '2021-03-04T10:34:36-06:00', User OID: 'PatientReportedOutcome (US3312225)', ODM File OID: '290cb4ee-aeec-4849-9336-8ffac68ead05'	System	04 Mar 2021 16:34:40
User entered '04 Mar 2021 10:34:36'	System	04 Mar 2021 16:34:40

US3312225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:06:15

US3312225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:06:15



US3312225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:06:15

US3312225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:06:15

US3312225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:54:06

US3312225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:04
User entered 'I'	System	21 Dec 2020 13:54:06

US3312225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:04

US3312225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:04

US3312225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:04

US3312225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:04



US3312225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:08

US3312225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User entered 'I'	System	21 Dec 2020 13:55:08

US3312225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:33:21

US3312225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:33:21

US3312225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:33:21

US3312225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:33:21

US3312225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:33:29

US3312225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User entered '1'	System	19 Jan 2021 16:33:29



US3312225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Mar 2021 22:37:41

US3312225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '16 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Mar 2021 22:37:41

US3312225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Mar 2021 22:37:41

US3312225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	(b) (4)	02 Mar 2021 22:37:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Mar 2021 22:37:45

US3312225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:51
User entered 'I'	System	02 Mar 2021 22:37:45

US3312225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:15

US3312225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:15



US3312225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:15

**US3312225**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:04:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 18:18:15

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

**US3312225**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:04:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00



US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

**US3312225**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:04:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:00



US3312225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:00

US3312225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:06

US3312225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:42
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:06

US3312225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:11

US3312225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:11

US3312225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:11

US3312225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 18:19:11

US3312225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:15



**US3312225**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:04:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:19:15

US3312225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:57

US3312225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:57

US3312225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:57

US3312225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:04:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:19:57

US3312225

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:20:00

**US3312225**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:04:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:20:00

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:49:22
User closed query 'Please verify and reconcile following missing pages: Diagnostic page and severity page, ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:35:11
Query 'Please verify and reconcile following missing pages: Diagnostic page and severity page, ' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:57
User opened query 'Please verify and reconcile following missing pages: Diagnostic page and severity page, ' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:12:06
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:31:17



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:49:22
User entered '08:00'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:31:17

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:05
User entered '09 Nov 2020 08:00'	System	10 Nov 2020 14:31:17

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:49:22
User entered 'Safety Call (Safety Call)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:31:17

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:04:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:49:22
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:31:17

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '04 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Dec 2020 17:48:23
User entered empty.	System	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 17:05:34
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:07:36

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '05 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Dec 2020 17:48:23
User entered empty.	System	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:08:12



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '06 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Dec 2020 17:48:23
User entered empty.	System	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:02

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '07 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Dec 2020 17:48:23
User entered empty.	System	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:09:41

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '08 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Dec 2020 17:48:23
User entered empty.	System	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:48:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:10:22

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '100'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97' F	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:11:07



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '10 Nov 2020'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '99'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '100.2' F	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:46:54

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 8 (Day 8)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '11 Nov 2020'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '99'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97.6' F	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	12 Nov 2020 18:22:26

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 9 (Day 9)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '12 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '100'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Severe (Severe)' reason for change:	Karol Moore (b) (4)	16 Nov 2020 19:47:02
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:45:57

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '13 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '99'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '102.0' F	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Severe (Severe)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:46:53



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 11 (Day 11)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '14 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97.0' F	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:47:42

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 12 (Day 12)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '15 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:48:14

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 13 (Day 13)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '16 Nov 2020'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '101.0' F	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 14 (Day 14)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '17 Nov 2020'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:13



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 15 (Day 15)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '18 Nov 2020'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97.2' F	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 16:56:26

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 16 (Day 16)'	(b) (4) Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '19 Nov 2020'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '94'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97.4' F	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16



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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	20 Nov 2020 19:49:16

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 17 (Day 17)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '20 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '97.6' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:28

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 18 (Day 18)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '21 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '100'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:55:49



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Day 19 (Day 19)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '100'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User entered '%'	System	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered '98.4' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:04:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:55
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 19:56:10

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:09:38
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:56
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'UPDATED' (Site from System).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:10
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	16 Nov 2020 19:50:03
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 9-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 9-NOV-2020 is reported under "Illness Visit Day 1" in PPD portal. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 06:27:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 9-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 9-NOV-2020 is reported under "Illness Visit Day 1" in PPD portal. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:04:11
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Nov 2020 19:50:03

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:04:11

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:23
User entered 'I'	System	16 Nov 2020 19:50:03



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:34
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30



US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30



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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Folder: Covid-19 Assessment 09 Nov 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30



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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:09:40
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 17:59:11
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly as it appears responses are missing.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 19:38:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:46:32
Query 'Per ETRTR: Please complete.' answered with 'updated' (Site from CRA).	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:37
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:31
User opened query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:26:54
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Un-verified.	(b) (4)	04 Mar 2021 17:58:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	04 Mar 2021 17:58:46
DataPoint Verified.	(b) (4)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4)	17 Nov 2020 21:24:30
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Un-verified.	(b) (4)	
	Karol Moore (b) (4)	04 Mar 2021 17:58:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 17:58:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4)	17 Nov 2020 21:24:30
	(b) (4)	

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Un-verified.	(b) (4)	04 Mar 2021 17:58:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	04 Mar 2021 17:58:46
DataPoint Verified.	(b) (4)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4)	17 Nov 2020 21:24:30
	(b) (4)	

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User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Un-verified.	(b) (4)	04 Mar 2021 17:58:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	04 Mar 2021 17:58:46
DataPoint Verified.	(b) (4)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4)	17 Nov 2020 21:24:30
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:46:38
Query 'Per ETRTR: Please complete.' answered with 'updated' (Site from CRA).	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:47
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Nov 2020 18:56:44
User opened query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:27:10
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:03:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Un-verified.	(b) (4)	04 Mar 2021 17:58:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	04 Mar 2021 17:58:46
DataPoint Verified.	(b) (4)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4)	17 Nov 2020 21:24:30
	(b) (4)	

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:24:46
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:24:30
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

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Generated On: 09 Jun 2021 17:04:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:04:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:18
User entered empty.	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:24:30

US3312225

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:04:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:34
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 17:06:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:34:41

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:47:28

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:47:28

**US3312225**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered '11 Nov 2020'	Karol Moore (b) (4) (b) (4)	11 Nov 2020 22:47:28

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:24:54



US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:24:54

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered '13 Nov 2020'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:24:54

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:25:03

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:25:03

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered '15 Nov 2020'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 16:25:03

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:05

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:05

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered '17 Nov 2020'	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:43:05



US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:55

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User closed query 'Please file lab requisition in subject source binder. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 03:22:02
Query 'Please file lab requisition in subject source binder. ' answered with 'SUBJECT DID NOT PROVIDE REQUISITION AT DROP-OFF. NOTED ON PACKING LIST' (Site from CRA).	Karol Moore (b) (4) (b) (4)	24 Nov 2020 19:09:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:40
User opened query 'Please file lab requisition in subject source binder. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:03:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:55

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:03:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:40
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:55

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	22 Dec 2020 16:46:16

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'No (N)'	Karol Moore (b) (4)	22 Dec 2020 16:46:16

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered empty.	Karol Moore (b) (4)	22 Dec 2020 16:46:16

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:49:11

US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:49:11



US3312225

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:58
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:56:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '07 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:49:11

US3312225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:18
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:18
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:18
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered 'SICKD1'	System	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '09:20'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16



US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered '09 Nov 2020 09:20'	System	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '71' in	Karol Moore (b) (4)	10 Nov 2020 15:13:16
DataPoint set to visible.	(b) (4) System	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '244.4' lb	Karol Moore (b) (4)	10 Nov 2020 15:13:16
DataPoint set to visible.	(b) (4) System	10 Nov 2020 15:12:26

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '97.0' F	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '77'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered 'bpm'	System	10 Nov 2020 15:13:16



US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '16'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered 'breaths/min'	System	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '106'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered 'mmHg'	System	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:47:53
User entered '79'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User entered 'mmHg'	System	10 Nov 2020 15:13:16

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24

US3312225

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24



US3312225

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:48:00
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:27

US3312225

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:48:00
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:27

US3312225

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:04:11

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:48:06
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:34

US3312225

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:04:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:48:06
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:13:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:25:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' answered with 'updated in edc' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 20:08:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 07DEC2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:28:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 16NOV2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:27:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07DEC2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 16NOV2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:27:13

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:45:59

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '07 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:45:59
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:45:59



US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered 'SICKD28'	System	08 Dec 2020 22:45:59

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'Yes (Y)'	(b) (4)	08 Dec 2020 22:46:34
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '07 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '11:25'	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:46:34
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered '07 Dec 2020 11:25'	System	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:46:34
	(b) (4)	
DataPoint set to visible.	System	08 Dec 2020 22:45:59

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:46:34
	(b) (4)	
DataPoint set to visible.	System	08 Dec 2020 22:45:59

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34



US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:46:34
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered empty.	(b) (4)	08 Dec 2020 22:46:34
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '71'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered 'bpm'	System	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered 'breaths/min'	System	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '113'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered 'mmHg'	System	08 Dec 2020 22:46:34



US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '85'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
User entered 'mmHg'	System	08 Dec 2020 22:46:34

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:04:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'Yes (Y)'	(b) (4)	08 Dec 2020 22:48:50
	Karol Moore (b) (4)	
	(b) (4)	

US3312225

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:04:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '07 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:48:50

US3312225

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:04:11**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	08 Dec 2020 22:48:57
	(b) (4)	

US3312225

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:04:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:04
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 16:55:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
User entered '07 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Dec 2020 22:48:57



US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:04:57

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 17:04:57

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Feb 2021 17:04:57

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:04:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 17:04:57

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:46:08

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:46:08



US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 17:08:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered 'I'	System	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:04:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered empty.	System	05 Feb 2021 17:08:48
User entered 'I'	System	05 Feb 2021 17:05:41

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:05:56



US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 17:05:56

US3312225

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:04:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '08:42'	(b) (4), (b) (6)	05 Feb 2021 17:05:56

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:04:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered '28 Jan 2021 08:42'	System	05 Feb 2021 17:05:56

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:06:06

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:04:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 17:06:06

US3312225

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:04:11**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered '08:41'	(b) (4), (b) (6)	05 Feb 2021 17:06:06

US3312225

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:04:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered '28 Jan 2021 08:41'	System	05 Feb 2021 17:06:06

US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 17:06:08



US3312225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:04:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:32
User entered '1'	System	05 Feb 2021 17:06:08

US3312225

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:04:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:47:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:48:03

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:31
User entered		
'USA-US300-2020-mRNA-1273-P301000011'	System	10 Nov 2020 18:19:26
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 18:19:26

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:51:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:51:37
Data point term sent to Coder	System	09 Nov 2020 21:50:34
User entered 'symptomatic covid 19'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:54:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:50:24
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '04 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:50:24



**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:04:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:43:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 17:43:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 17:43:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 07:11:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 17:43:36
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:43:32
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	20 Nov 2020 17:43:26
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 17:43:26
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:01:35
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:04:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24



US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24



US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:50:24



US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:58:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:48:15
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:44:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	20 Nov 2020 17:43:45
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:01:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:48:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'Per DM CLR: SAE Narrative = IN THE ED, SUBJECT HAD A NEGATIVE CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 09:29:17
Query 'Per DM CLR: SAE Narrative = IN THE ED, SUBJECT HAD A NEGATIVE CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'CXR is diagnostic not a procedure-NA' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 21:11:44
User opened query 'Per DM CLR: SAE Narrative = IN THE ED, SUBJECT HAD A NEGATIVE CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:19:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:48:15
User closed query 'PV Query: Please confirm the subject did not have occupational risk or living /circumstance risk.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 15:10:24
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 15:10:22
Query 'PV Query: Please confirm the subject did not have occupational risk or living /circumstance risk.' answered with 'RISK OF COMMUNITY ONGOING PERSON TO PERSON TRANSMISSION' (Site from Safety).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 22:00:31
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test and severity assessment.' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4) (b) (4)	17 Nov 2020 21:58:32
User opened query 'PV Query: Please confirm the subject did not have occupational risk or living /circumstance risk.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:03:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:02:02
User entered 'Subject called clinic at 0800 this morning to report COVID symptoms and a positive COVID-19 test in the ED last night. He reports that he called his PCP on 08 Nov 2020 with symptoms and was instructed to go to the local ED for testing. In the ED, subject had a negative CXR and was instructed to take prescribed dexamethasone, as well as OTC Zinc, calcium, and vitamin D. At illness visit today, subject reports symptom onset on 04 Nov 2020 with mild chills, cough, muscle aches, body aches, headache, and fatigue. He reports being afebrile apart from tmax of 100.7 F on 07 Nov 2020. Subject also reports two episodes of loose stool, one on 06 Nov 2020, and the other on 07 Nov 2020. Reports runny nose from 06 Nov 2020 to 08 Nov 2020. Subject also reports mild shortness of breath beginning today, spo2 100% today. Other vital signs and physical exam unremarkable as well. Acetaminophen taken yesterday for muscle aches, body aches, and headache. Subject reports no known sick contacts in recent weeks.'	(b) (4), (b) (6)	09 Nov 2020 21:50:24

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 17:04:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 21:50:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:04:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 21:50:24

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:15:14
User entered 'USA-US300-2021-mRNA-1273-P301000012'	System	05 Feb 2021 17:52:58
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:52:58
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:35:50
User entered 'USA-US300-2020-mRNA-1273-P301000011'	(b) (4), (b) (6)	05 Feb 2021 17:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 21:16:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 21:16:04
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 21:14:25
User entered 'Transient ischemic attack'	(b) (4), (b) (6)	04 Feb 2021 21:14:10



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:04:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:08:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:08:18
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:14:10



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:33:45
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 22:26:19
User entered empty.	System	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	04 Feb 2021 21:14:29
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Feb 2021 21:14:10
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:29
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10



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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'PV Query: As the last dose of study drug was given on 21 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 19:21:18
User closed query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:26:12
Query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 22:00:02
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020 , please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	15 Feb 2021 21:59:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:59:14
User opened query 'PV Query: As the last dose of study drug was given on 21 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 22:25:46
User opened query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:45:50
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:12:58
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:08:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 17:08:18
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 19:04:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 13:54:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'email with medical records sent 17Feb2021' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 11:55:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 22:27:04

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	04 Feb 2021 21:14:10

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:14:10

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:27:20
Query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'NOT APPLICABLE. PER CRA GUIDANCE, DIAGNOSTIC PROCEDURES ARE NOT REPORTABLE IN CRF' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:31:15
User opened query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:59:04
User closed query 'PV Query: please provide results of MRA/MRI and carotid doppler when available. If no results are available, please confirm ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:14:05
Query 'PV Query: please provide results of MRA/MRI and carotid doppler when available. If no results are available, please confirm ' answered with 'Per subject-carotid doppler normal-no official med record subject did not have MRA/MRI' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:48:18
User opened query 'PV Query: please provide results of MRA/MRI and carotid doppler when available. If no results are available, please confirm ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:01:34
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI and carotid doppler). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:15:06



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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI and carotid doppler). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'medical records sent to safety on 17Feb2021' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:07:41
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI and carotid doppler). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 19:03:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 13:54:37
User closed query 'Per DM CLR: Narrative = MRA/MRI WHICH IS YET TO BE COMPLETED. Please review and confirm if these were already performed. If yes, please ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:42:56
User closed query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:42:54
Query 'Per DM CLR: Narrative = MRA/MRI WHICH IS YET TO BE COMPLETED. Please review and confirm if these were already performed. If yes, please ensure that these are captured in the appropriate eCRF. ' answered with 'NA,not a procedure' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:55:52

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'email with medical records sent 17Feb2021' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 11:55:29
Query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'NA-not a procedure, we are not listing every diagnostic' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:55:07
User opened query 'Per DM CLR: Narrative = MRA/MRI WHICH IS YET TO BE COMPLETED. Please review and confirm if these were already performed. If yes, please ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:38:00
User opened query 'Per DM CLR: Narrative = CAROTID DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:37:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (MRA/MRI). Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 22:26:42

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is a 54 year old gentleman with h/o atherosclerosis (s/p bypass surgery), hyperlipidemia, HTN, hypothyroidism and symptomatic COVID-19 in November 2020 who at his decision visit on 1/28/2021 reported transient memory loss and speech disturbances on 1/24/2021. He had been instructed by his PCP to go to ED, but he refused and was seen by PCP the next day, on 1/25/2021. PCP's office visit medical records show that he had a normal exam with final assessment of Transient Ischemic Attack (TIA); further evaluations were ordered, including carotid Doppler (which per subject's verbal report on 2/4/21 was normal) and MRA/MRI which is yet to be completed. Clopidogrel 75mg PO daily was added to his daily medication regimen which already included aspirin 81mg PO daily. Although subject reported symptoms on 1/28/2021, event not determined to be SAE until review of medical records on 2/3/2021 and discussion with PI on 2/4/2021. This is an SAE for a medically important event of TIA, not related to IP. Will close after review of diagnostic procedure results'	(b) (4), (b) (6)	04 Feb 2021 21:14:10

US3312225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:04:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 21:14:10

US3312225

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 09 Jun 2021 17:04:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 21:14:10

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 16:25:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 16:25:45
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 16:24:22
User entered 'WORSENING HYPERLIPIDEMIA'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	



US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '15 Oct 2020'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:24:21

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Apr 2021 16:24:31
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	09 Apr 2021 16:24:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Apr 2021 16:24:21
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

**US3312225**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:04:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:24:21



US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	



US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4)	09 Apr 2021 16:24:31
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 09 Jun 2021 17:04:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:04:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	09 Apr 2021 16:24:21
	(b) (4)	

US3312225

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 09 Jun 2021 17:04:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 16:24:21

US3312225

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 09 Jun 2021 17:04:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 16:24:21

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:04:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:47:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:25:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:51:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 15:55:42



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:21:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:21:39
Data point term sent to Coder	System	01 Sep 2020 16:01:12
User entered 'repatha (evolocumab)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User closed query 'Per DM CLR: Please note that this condition with this time frame is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:49:16
Query 'Per DM CLR: Please note that this condition with this time frame is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Med Hx updated. Thanks. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	23 Oct 2020 14:19:22
User opened query 'Per DM CLR: Please note that this condition with this time frame is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:13:24
User entered 'hyperlipidemia'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '140'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'every 15 days'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4)	01 Sep 2020 16:00:31
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:00:31

**US3312225**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 16:00:31



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 16:00:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 16:00:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 10:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 10:09:41
Data point term sent to Coder	System	01 Sep 2020 16:03:23
User entered 'insulin degludec'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Type 2 diabetes mellitus'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '50'	Karol Moore (b) (4)	01 Sep 2020 16:03:01
	(b) (4)	

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'units'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4)	01 Sep 2020 16:03:01
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4)	01 Sep 2020 16:03:01
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:03:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:03:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
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)	01 Sep 2020 16:05:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:05:53
Data point term sent to Coder User entered 'aspirin'	System Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:32 01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:18:11
Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' answered with 'Updated. Thank you. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:40:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:40:06
User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 10:54:38
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'cardiovascular prophylaxis'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '81'	Karol Moore (b) (4)	01 Sep 2020 16:04:08
	(b) (4)	



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4)	01 Sep 2020 16:04:08
	(b) (4)	



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:04:08

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:04:08

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:07:45
Data point term sent to Coder	System	01 Sep 2020 16:06:37
User entered 'atorvastatin'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'hyperlipidemia'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '40'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 18:00:29
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:29
User entered 'UN Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 18:00:29
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User entered '1'	System	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User entered '1'	System	01 Sep 2020 16:06:06

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:47
User entered '804 (804)'	System	01 Sep 2020 16:06:06



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:08:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:08:48
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 16:07:38
User entered 'carvedilol'	Karol Moore (b) (4)	01 Sep 2020 16:07:02
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'hypertension'	Karol Moore (b) (4)	01 Sep 2020 16:07:02
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '3.125'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'twice daily (BID)'	Karol Moore (b) (4)	01 Sep 2020 16:07:02
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User closed query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:50:23
Query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'Med Hx updated. Thanks. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	23 Oct 2020 14:19:44
User opened query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:14:03
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:07:02

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 16:07:02



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:07:02

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:07:02

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:09:49
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 Sep 2020 16:09:49
Data point term sent to Coder	System	01 Sep 2020 16:08:42
User entered 'fenofibrate'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'hyperlipidemia'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '145'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User closed query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:50:57
Query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'Medical Hx updated. Thanks. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	23 Oct 2020 14:20:09
User opened query 'Per DM CLR: The corresponding MH condition has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:14:31
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:08:33

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:08:33

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:10:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:10:53
Data point term sent to Coder User entered 'lisinopril'	System Karol Moore (b) (4)	01 Sep 2020 16:09:43 01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '5'	Karol Moore (b) (4)	01 Sep 2020 16:09:10
	(b) (4)	



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:09:10

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:09:10

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 16:11:46
Data point term sent to Coder	System	01 Sep 2020 16:10:45
User entered 'levothyroxine'	Karol Moore (b) (4)	01 Sep 2020 16:09:54
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'hypothyroidism'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '75'	Karol Moore (b) (4)	01 Sep 2020 16:09:54
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mcg'	Karol Moore (b) (4)	01 Sep 2020 16:09:54
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4)	01 Sep 2020 16:09:54
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:09:54

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:09:54



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 16:11:46
Data point term sent to Coder	System	01 Sep 2020 16:10:45
User entered 'metformin'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Type 2 diabetes mellitus'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '1000'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Sep 2020 16:10:34

**US3312225**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 16:10:34



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:10:34

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 16:10:34

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
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)	10 Nov 2020 15:56:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:56:36
Data point term sent to Coder	System	10 Nov 2020 15:41:13
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'I'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'injection'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, also given the Start and Stop Dates. Please update the Frequency as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 19:52:53
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, also given the Start and Stop Dates. Please update the Frequency as appropriate.' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Dec 2020 14:52:17
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	28 Dec 2020 14:52:00
User entered 'once (ONCE)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Dec 2020 14:52:00
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated, also given the Start and Stop Dates. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 10:32:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '26 Oct 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '26 Oct 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:40:27

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User entered empty.	System	28 Dec 2020 14:52:00
User entered '2'	System	10 Nov 2020 15:40:27

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User entered empty.	System	28 Dec 2020 14:52:00
User entered '1'	System	10 Nov 2020 15:40:27

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:06
User entered empty.	System	28 Dec 2020 14:52:00
User entered '804 (804)'	System	10 Nov 2020 15:40:27

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
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)	10 Nov 2020 15:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:42:36
Data point term sent to Coder	System	10 Nov 2020 15:42:14
User entered 'acetaminophen'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'syptomatic covid-19'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '1000'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '08 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:22:38
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:22:38
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:22:38
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:41:40
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:41:40

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User entered empty.	System	10 Nov 2020 15:41:40

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User entered empty.	System	10 Nov 2020 15:41:40

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:09
User entered empty.	System	10 Nov 2020 15:41:40

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:57:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:57:37
Data point term sent to Coder	System	10 Nov 2020 15:42:15
User entered 'vitamin d3'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '4000'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'IU (IU)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	22 Dec 2020 15:23:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 15:23:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:42:05
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:23:15
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:23:15
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:42:05
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:05

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User entered '1'	System	10 Nov 2020 15:42:05

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User entered '1'	System	10 Nov 2020 15:42:05

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:12
User entered '804 (804)'	System	10 Nov 2020 15:42:05



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:58:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:58:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:43:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:43:36
Data point term sent to Coder	System	10 Nov 2020 15:43:17
User entered 'vitamin c'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '500'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	22 Dec 2020 15:23:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 15:23:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:42:28
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:23:40
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:23:40
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:42:28
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:42:28

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User entered '2'	System	10 Nov 2020 15:42:28



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User entered '1'	System	10 Nov 2020 15:42:28

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:17
User entered '804 (804)'	System	10 Nov 2020 15:42:28

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CITRATE + D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:45:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:45:50
Data point term sent to Coder	System	10 Nov 2020 15:43:18
User entered 'calcium citrate 630mg/ d3 12.5mg'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '2'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:24:10
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:24:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:24:10
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:24:10
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:43:18



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:18

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered '1'	System	10 Nov 2020 15:43:18

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered '1'	System	10 Nov 2020 15:43:18

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered '804 (804)'	System	10 Nov 2020 15:43:18

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'SUBJECT DID NOT START THIS CON MED UNTIL AFTER THE DAY 29 DOSING ADMINISTRATION, <20MG/DAY AND <14 DAYS. DOES NOT MEET EXCLUSION CRITERIA #12.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:27:18
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	Monica Atwood (b) (4) (b) (4)	21 Dec 2020 17:45:02
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:43:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:00:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:00:37
Data point term sent to Coder	System	10 Nov 2020 15:44:19
User entered 'dexamethasone'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '6'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	22 Dec 2020 15:24:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 15:24:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:43:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:24:30
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:24:30
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:43:42
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User entered '1'	System	10 Nov 2020 15:43:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User entered '1'	System	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:04:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:24
User entered '804 (804)'	System	10 Nov 2020 15:43:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:45:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:45:39
Data point term sent to Coder	System	10 Nov 2020 15:44:19
User entered 'zinc'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '100'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '09 Nov 2020'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	
	Monica Atwood (b) (4)	22 Dec 2020 15:24:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 15:24:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Nov 2020 15:44:01
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Un-verified.	(b) (4)	22 Dec 2020 15:24:47
User entered '19 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 15:24:47
DataPoint Verified.	(b) (4)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4)	10 Nov 2020 15:44:01
	(b) (4)	

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Nov 2020 15:44:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User entered '1'	System	10 Nov 2020 15:44:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User entered '1'	System	10 Nov 2020 15:44:01

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:29
User entered '804 (804)'	System	10 Nov 2020 15:44:01



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:52:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:52:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
Data point term sent to Coder	System	24 Nov 2020 15:24:42
User entered 'erythromycin'	Karol Moore (b) (4)	24 Nov 2020 15:24:00
	(b) (4)	

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '500'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '13 Nov 2020'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Per Convalescent period comments page this medication prescribed for 5 days. Please verify and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:20:53
Query 'Per Convalescent period comments page this medication prescribed for 5 days. Please verify and update if needed.' answered with 'UPDATED PER PROVIDER' (Site from CRA).	Karol Moore (b) (4) (b) (4)	24 Nov 2020 19:03:31
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 19:03:24
User entered '18 Nov 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	24 Nov 2020 19:03:24
User opened query 'Per Convalescent period comments page this medication prescribed for 5 days. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '20 Nov 2020'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:24:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User entered '1'	System	24 Nov 2020 15:24:00



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User entered '1'	System	24 Nov 2020 15:24:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:32
User entered '804 (804)'	System	24 Nov 2020 15:24:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: HYDROXYCHLOROQUINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 15:28:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 15:28:14
Data point term sent to Coder	System	24 Nov 2020 15:22:40
User entered 'hydroxychloroquine'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'symptomatic covid-19'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '200'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '13 Nov 2020'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered '20 Nov 2020'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:57:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Nov 2020 15:22:25

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User entered '1'	System	24 Nov 2020 15:22:25

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User entered '1'	System	24 Nov 2020 15:22:25

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:37
User entered '804 (804)'	System	24 Nov 2020 15:22:25

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:13:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:13:52
	(b) (4)	
Data point term sent to Coder	System	05 Feb 2021 20:44:06
User entered 'Clopidogrel'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'transient ischaemic attack'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	05 Feb 2021 20:43:57



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 20:43:57



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:43:57

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 20:43:57

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Feb 2021 09:15:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:15:51
Data point term sent to Coder	System	05 Feb 2021 21:12:29
Data point term sent to Coder	System	05 Feb 2021 20:54:11
User entered 'clindamycin 1%'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 21:12:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:53:44



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'PREVENT RASH after HAIRCUT'	(b) (4), (b) (6)	05 Feb 2021 21:11:48
reason for change: Data Entry Error		
User entered 'prevent rash at haircut'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'application'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:53:44



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'un UNK 2011'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 20:53:44

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 20:53:44



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 10:28:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:28:49
Data point term sent to Coder	System	07 Apr 2021 17:59:00
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 17:58:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:44:48
Data point term sent to Coder	System	05 Feb 2021 20:57:13
User entered 'testosterone'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Hypotestosteronemia'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '120'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:56:43



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Per CDM: Please consider selecting "Transdermal" from the dropdown instead of selecting "Other" and writing "Transdermal". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:28:23
Query 'Per CDM: Please consider selecting "Transdermal" from the dropdown instead of selecting "Other" and writing "Transdermal". Thank you!' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:58:57
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:58:49
User opened query 'Per CDM: Please consider selecting "Transdermal" from the dropdown instead of selecting "Other" and writing "Transdermal". Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:18:43
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:58:49
User entered 'transdermal'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:56:43



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:56:43

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 20:56:43

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: UBIQUINONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Feb 2021 13:58:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 13:58:41
Data point term sent to Coder	System	05 Feb 2021 21:00:15
User entered 'ubiquinone'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Health maintenance'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '200'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:59:42



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 20:59:49
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		05 Feb 2021 20:59:49
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		05 Feb 2021 20:59:42
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 20:59:42



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:59:42

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 20:59:42

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:51:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:51:58
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 16:55:58
Data point term sent to Coder	System	09 Apr 2021 16:29:32
Coding entries removed.	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:28:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:18:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:18:56
Data point term sent to Coder	System	05 Feb 2021 21:03:21
User entered 'atorvastatin'	(b) (4), (b) (6) (b) (4)	05 Feb 2021 21:02:29

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'WORSENING OF HYPERLIPIDEMIA' reason for change: Data Entry Error	Karol Moore (b) (4)	09 Apr 2021 16:28:57
	(b) (4)	
User entered 'hyperlipidemia'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '80'	(b) (4), (b) (6)	05 Feb 2021 21:02:29



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with CM# 4 (UNK 2010 - ongoing). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:28:34
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with CM# 4 (UNK 2010 - ongoing). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	07 Apr 2021 18:00:57
' answered with 'UPDATED.' (Site from DM).		
User entered 'UN Nov 2020' reason for change:	(b) (4), (b) (6)	07 Apr 2021 18:00:51
Data Entry Error		
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with CM# 4 (UNK 2010 - ongoing). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	18 Feb 2021 15:00:58
' (Site from DM).		
User entered 'un UNK 2020'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:02:29



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:02:29

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:02:29

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 21:04:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:04:49
Data point term sent to Coder	System	05 Feb 2021 21:04:21
User entered 'empagliflozin '	(b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered '25'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:04:16



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:04:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:04:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 21:04:24
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:04:16
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:04:16

**US3312225**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:04:16

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:04:16



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:17:05
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EICOSAPENTAENOIC ACID, PRODUCTSYNONYM: ICOSAPENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 16:28:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:28:42
Data point term sent to Coder	System	09 Apr 2021 16:27:29
Data point term sent to Coder	System	09 Apr 2021 16:26:28
Coding entries removed.	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:26:19
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'CONFIRMED WORSENING. SEE AE' (Site from DM).	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:23:15
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:02:12

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EICOSAPENTAENOIC ACID, PRODUCTSYNONYM: ICOSAPENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:06:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:06:49
Data point term sent to Coder	System	05 Feb 2021 21:06:26
User entered 'icosapent'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'WORSENING OF HYPERLIPIDEMIA' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:26:40
User entered 'EXACERBATION OF HYPERLIPIDEMIA' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:26:19
User entered 'hyperlipidemia'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'g (g)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	09 Apr 2021 16:22:46
	(b) (4)	
User entered 'un Oct 2020'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:06:24



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:06:24

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:06:24

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Feb 2021 21:08:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 21:08:49
Data point term sent to Coder	System	05 Feb 2021 21:08:27
User entered 'omeprazole'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'heartburn'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 21:07:31



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'un Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:04:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:07:31



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:07:31

**US3312225**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:07:31

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:07:31

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 21:10:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 21:10:01
Data point term sent to Coder	System	05 Feb 2021 21:09:27
User entered 'calcium carbonate'	(b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'heartburn'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00



US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered '500'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00



US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:04:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 21:09:18
User entered 'un Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 21:09:18
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).		05 Feb 2021 21:09:00
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:04:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:09:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:04:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User entered empty.	System	05 Feb 2021 21:09:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User entered empty.	System	05 Feb 2021 21:09:00

US3312225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:04:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:26:31
User entered empty.	System	05 Feb 2021 21:09:00

US3312225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:04:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:42
User closed query ' Per ETRTR: According to narrative concomitant procedures were performed for SAE ,Transient Ischemic attack, please update this folder in order to add the respective procedures performed. thanks!' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:57:51
Query ' Per ETRTR: According to narrative concomitant procedures were performed for SAE ,Transient Ischemic attack, please update this folder in order to add the respective procedures performed. thanks!' answered with 'NOT APPLICABLE. PER CRA GUIDANCE, DIAGNOSTIC PROCEDURES ARE NOT REPORTABLE IN CRF' (Site from CRA).	Karol Moore (b) (4) (b) (4)	09 Apr 2021 16:32:29
User opened query ' Per ETRTR: According to narrative concomitant procedures were performed for SAE ,Transient Ischemic attack, please update this folder in order to add the respective procedures performed. thanks!' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 23:21:00
Query 'Per ETRTR: According to narrative concomitant procedures were performed for SAE ,Transient Ischemic attack, please update this folder in order to add the respective procedures performed. thanks!' canceled (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 23:20:49
User opened query 'Per ETRTR: According to narrative concomitant procedures were performed for SAE ,Transient Ischemic attack, please update this folder in order to add the respective procedures performed. thanks!' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 23:12:44
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 17:06:50



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Un-reviewed for Safety.	(b) (4)	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54



**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
User entered '10/Nov/2020 18:19'	System	10 Nov 2020 18:19:54

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 18:19:54

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Un-reviewed for Safety.	(b) (4)	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
User entered '18/Nov/2020 10:11'	System	18 Nov 2020 15:11:37

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 17:57:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 15:11:37

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Un-reviewed for Safety.	(b) (4)	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Un-reviewed for Safety.	(b) (4)	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26



**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '30/Nov/2020 17:57'	(b) (4) System	30 Nov 2020 17:57:27

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 13:44:27
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 17:57:27

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Un-reviewed for Safety.	(b) (4)	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '01/Dec/2020 08:49'	(b) (4) System	01 Dec 2020 13:49:36

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:36
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 13:49:36



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'USA-US300-2020-MRNA-1273-P301000011'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
	(b) (4)	
Un-reviewed for Safety.	System	05 Feb 2021 17:52:58
User entered 'No (N)'	System	05 Feb 2021 17:52:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:36:36
Un-reviewed for Safety.	System	05 Feb 2021 17:35:31
DataPoint Un-verified.	System	05 Feb 2021 17:35:31
User entered 'Yes (Y)'	System	05 Feb 2021 17:35:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'No (N)'	System	10 Nov 2020 18:19:26



US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Carlos'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Fierro'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '16300 College Blvd'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'Shawnee'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered 'KS'	System	10 Nov 2020 18:19:26

**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:19:47
User entered '66219'	System	10 Nov 2020 18:19:26

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:52:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:11:29
User entered 'US'	System	10 Nov 2020 18:19:54

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Feb 2021 17:36:14
User entered '4'	System	01 Dec 2020 13:49:36
User entered '3'	System	30 Nov 2020 17:57:27
User entered '2'	System	18 Nov 2020 15:11:37
User entered '1'	System	10 Nov 2020 18:19:54



**US3312225**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '05/Feb/2021 12:36'	(b) (4) System	05 Feb 2021 17:36:14

US3312225

Folder: SAE USA-US300-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:31:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:36:36
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 17:36:14

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '05/Feb/2021 12:54'	(b) (4) System	05 Feb 2021 17:54:05

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 17:54:05

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58



**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58



**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '16/Feb/2021 14:22'	(b) (4) System	16 Feb 2021 19:22:40

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:51
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 19:22:40

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '18/Feb/2021 13:31'	(b) (4) System	18 Feb 2021 18:31:06

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:15:53
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 18:31:06



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05



**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '12/Mar/2021 10:16'	(b) (4) System	12 Mar 2021 15:16:46

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:16:46

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'USA-US300-2021-MRNA-1273-P301000012'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58



**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'No (N)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Yes (Y)'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Carlos'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Fierro'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '16300 College Blvd'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'Shawnee'	System	05 Feb 2021 17:52:58

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'KS'	System	05 Feb 2021 17:52:58

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered '66219'	System	05 Feb 2021 17:52:58



US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:04:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:54:10
User entered 'US'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:04:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 14:14:33
User entered '4'	System	12 Mar 2021 15:16:46
User entered '3'	System	18 Feb 2021 18:31:06
User entered '2'	System	16 Feb 2021 19:22:40
User entered '1'	System	05 Feb 2021 17:54:05

**US3312225**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:04:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered '18/Mar/2021 10:14'	(b) (4) System	18 Mar 2021 14:14:33

US3312225

Folder: SAE USA-US300-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:04:11

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:45:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:14:33