

US3312548 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:18:49

All time stamps listed in this document are displayed in GMT

US3312548

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

[Participant ID](#)

US3312548

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

US3312548

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 20:49:42

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Date of Informed Consent (*dd MMM yyyy*) 08 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 20:49:42

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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) 23 Feb 2021 20:49:42

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	HYPERTENSION
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 (3)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	HYPERCHOLESTEROLEMIA
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 (4)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	BILATERAL KNEE OSTEOARTHRITIS
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) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	RIGHT KNEE MENISCUS TEAR
Start date (dd MMM yyyy)	UN UNK 2009
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	LEFT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN UNK 2002
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Condition	BILATERAL HEARING LOSS
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 (11)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:35
Height (<i>xxx.x</i>)	69.5 in
Weight (<i>xxx.x</i>)	219 lb
BMI (<i>xxx.x</i>)	31.94364 kg/m ²
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) 23 Feb 2021 20:49:42

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 20:49:42

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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 ☒

Specify

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) 23 Feb 2021 20:49:42

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	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) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 20:49:42

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What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 190313

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) 23 Feb 2021 20:49:42

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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) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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)	08 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:35
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 16:25
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 15:50

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) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	15:19 (24 HR)
Collection date and time (derived)	08 SEP 2020 15:19

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:10	08 SEP 2020 15:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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: 11 Aug 2021 22:18:49

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 16:33

PC Open Date & Time

08 SEP 2020 16:10

PC Close Date & Time

08 SEP 2020 18:40

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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 98.7 °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	08 SEP 2020 20:24
PC Open Date & Time	08 SEP 2020 19:35
PC Close Date & Time	09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

10 SEP 2020 13:10

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

96.8 °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

11 SEP 2020 12:46

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

13 SEP 2020 17:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

14 SEP 2020 13:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

08 SEP 2020 16:33

PC Open Date & Time

08 SEP 2020 16:10

PC Close Date & Time

08 SEP 2020 18:40

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

08 SEP 2020 20:25

PC Open Date & Time

08 SEP 2020 19:35

PC Close Date & Time

09 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

09 SEP 2020 12:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

10 SEP 2020 13:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	11 SEP 2020 12:47
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

12 SEP 2020 15:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

13 SEP 2020 17:29

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

14 SEP 2020 13:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 16:34
PC Open Date & Time	08 SEP 2020 16:10
PC Close Date & Time	08 SEP 2020 18:40

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:26
PC Open Date & Time	08 SEP 2020 19:35
PC Close Date & Time	09 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 13:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

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)

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

60 of 2655

EAB) (1725)

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:29
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 13:58
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3312548

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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.

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3312548

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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

OCCURRED DURING
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT3

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 08:54
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

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.

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 NOV 2020
Collection time (00:00-23:59)	09:09 (24 HR)
Collection date and time (derived)	10 NOV 2020 09:09

US3312548

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 20:49:42

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 NOV 2020 09:16:18
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

16 NOV 2020 07:58:43

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 75
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	22 NOV 2020 08:47:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 82
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 NOV 2020 10:03:01
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 08:47:09
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 07:26:49

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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	24 DEC 2020 07:41:53
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 17:59:27
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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	07 JAN 2021 06:05:07
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

18 JAN 2021 15:57:36

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

21 JAN 2021 08:31:37

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

28 JAN 2021 02:12:40

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

04 FEB 2021 09:23:59

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

11 FEB 2021 09:38:25

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 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	18 FEB 2021 07:38:12
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

25 FEB 2021 08:12:51

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 07:51:00

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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	12 MAR 2021 19:42:47
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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	18 MAR 2021 08:06:58
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 13:18:59
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

01 APR 2021 02:00:40

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

09 APR 2021 21:02:11

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

16 APR 2021 11:48:30

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 12:38:26

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 08:01:14
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐
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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 607

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

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

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

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

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

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

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

04 AUG 2022 00:01

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08 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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05 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 SEP 2022 00:01

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12 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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="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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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 <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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 OCT 2022 00:01
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Patient Cloud Close Date & Time	31 OCT 2022 23:59
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US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3312548

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:18:49

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 07:51:31

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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) _____

US3312548

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3312548

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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

Collection date (dd MMM yyyy)	22 MAR 2021
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Collection time (00:00-23:59)	10:39 (24 HR)
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Collection date and time (derived)	22 MAR 2021 10:39
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US3312548

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Date of Contact	07 OCT 2020
Time of Contact	07:53
Date and Time of Contact (derived)	07 OCT 2020 07:53
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>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 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 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Form: Symptom Log (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

Date	07 OCT 2020
------	-------------

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

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

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

Temperature	99.0 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 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)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 (6)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 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 checked="" type="checkbox"/>
	Mild	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.8 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 (7)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 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 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 (8)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 (8)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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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Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 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 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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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

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	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 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 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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 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 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 (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Form: Symptom Log (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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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) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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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Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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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Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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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US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

Date	19 OCT 2020
------	-------------

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Date of Visit 07 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 07 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 OCT 2020
Day 5	Yes	11 OCT 2020
Day 7	Yes	13 OCT 2020
Day 9	Yes	15 OCT 2020
Day 14	Yes	20 OCT 2020
Day 21	Yes	27 OCT 2020
Day 28	Yes	03 NOV 2020

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

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

Visit date (dd MMM yyyy)	07 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 12:35
Height (xxx.x)	69 in
Weight (xxx.x)	205 lb
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	107 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3312548

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SICKD28

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 09:16
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 NOV 2020

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

US3312548

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 NOV 2020

US3312548

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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

Visit date (dd MMM yyyy)	12 JAN 2021
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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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US3312548

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312548

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3312548

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:32
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312548

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:01
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3312548

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

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3312548

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

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 14:30

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

US3312548

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

12:52 (24 HR)

Collection date and time (derived)

12 JAN 2021 12:52

US3312548

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00 - 23:59)	12:51
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Collection Date and Time (derived)	12 JAN 2021 12:51
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US3312548

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

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312548

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3312548

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:42

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 18:14:42

Generated On: 11 Aug 2021 22:18:49

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)	09 FEB 2021
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 13:15
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 18:14:42

Generated On: 11 Aug 2021 22:18:49

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	09 FEB 2021
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 14:21
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3312548

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:24

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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

US3312548

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 09 FEB 2021

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 09 FEB 2021 13:50

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

US3312548

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	OLD57

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

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) _____

US3312548

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3312548

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	10:39 (24 HR)
Collection date and time (derived)	22 MAR 2021 10:39

US3312548

Folder: **Unscheduled 08 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Visit Date	08 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 16:30
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>)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Visit Date	10 NOV 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 09:00
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:06:51

Generated On: 11 Aug 2021 22:18:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

AEID	USA-US300-2020-MRNA-1273-P30 1000003
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)	03 OCT 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)	15 OCT 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 (3)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

SUBJECT HAS ROUTINE
CARDIAC STRESS TEST
SCHEDULED WHICH REQUIRED
PRE EXAM COVID TEST WHICH
RESULTED IN POSITIVE
RESULT. SUBJECT CALLED SITE
SAME DAY RESULT GIVEN AND
SWAB DONE AT SITE WHICH
WAS POSITIVE. SUBJECT HAD
NOT RECOGNIZED SYMPTOMS
UNTIL AFTER TEST RESULTS
GIVEN-THEN REPORTED TO
SITE. POSITIVE RESULTS
RECEIVED AT SITE TODAY.
SUBJECT IS FEELING BETTER
WITH ONLY MILD FATIGUE
AND COUGH ONGOING., O2
SATS REMAINED HIGH
90S-100%, TOOK OTC MEDS
ONLY. DID NOT SEEK
ADDITIONAL MEDICAL CARE.
UPDATE: 10NOV2020: SUBJECT
HAS CARDIAC STRESS TEST
DONE WHICH WAS NORMAL,
DONE ROUTINELY EVERY 5
YRS, NOT DUE TO SYMPTOMS.

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 (4)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

AEID

Adverse event

EXACERBATION OF
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 20:47:49

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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	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	
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 (5)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

AEID	
Adverse event	LOW HEMOGLOBIN
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)	17 FEB 2021
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

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 20:47:49

Generated On: 11 Aug 2021 22:18:49

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

Data signed: (b) (4) 07 Apr 2021 18:14:22

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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) 07 Apr 2021 18:14:22

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Name of Medication METHYLPHENIDATE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 OCT 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 (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

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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 (2)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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)	16 OCT 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 (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (3)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication PRALUENT PEN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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

ONCE EVERY 14 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 (4)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (5)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

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 (6)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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 2012	
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) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication CONTINUOUS POSITIVE
AIRWAY PRESSURE

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTIVE SLEEP APNEA

Dose per administration 1

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

If dose unit is Other, specify NASAL MASK

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 NIGHTLY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
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 (8)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication ACETAMINOPHEN
325MG/PHENYLEPRINE 5MG

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	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)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 OCT 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"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication LISINOPRIL
20MG/HYDROCHLOROTHIAZID
E
12.5MG

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF
HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	17 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication FERRIC CITRATE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

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

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 18:14:22

Generated On: 11 Aug 2021 22:18:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 OCT 2020	CARDIAC STRESS TEST	Diagnostic	
14 DEC 2020	LEFT KNEE ARTHROPLASTY	Medical History	

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 07 Apr 2021 18:14:23

Generated On: 11 Aug 2021 22:18:49

Date of dosing discontinuation (dd MMM yyyy) 12 OCT 2020

Primary reason for dosing discontinuation

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

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

US3312548

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:18:49

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 ☐

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

SAEID	USA-US300-2020-MRNA-1273-P301000003
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)	3

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

SAEID	USA-US300-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	13/OCT/2020 15:20
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

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

SAEID	USA-US300-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	22/OCT/2020 21:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 18:14:43

Generated On: 11 Aug 2021 22:18:49

SAEID	USA-US300-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	27/OCT/2020 15:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312548 (Prod: Johnson County Clin-Trials)

US3312548

Form: Participant Creation

Generated On: 11 Aug 2021 22:18:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'US3312548'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:04:43

US3312548

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:04:45

US3312548

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'SCRN'	System	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:04:46

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '65'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'YEARS'	System	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '65'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Male (M)'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'I'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	Christa Estrada (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:10:49
User entered '8 Sep 2020'	Karol Moore (b) (4)	08 Sep 2020 20:57:59
	(b) (4)	

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Sep 2020'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2020'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 19:04:45

US3312548

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'I'	System	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	Christa Estrada (b) (4)	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:18:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:10:32

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Psychiatric disorders, HLGt: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:12:41
Data point term sent to Coder	System	02 Oct 2020 16:12:02
User entered 'attention deficit disorder'	Karol Moore (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2000'	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2000'	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
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)	02 Oct 2020 16:13:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:13:43
Data point term sent to Coder	System	02 Oct 2020 16:13:04
User entered 'hypertension'	Karol Moore (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2017'	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2017'	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:14:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:14:44
Data point term sent to Coder	System	02 Oct 2020 16:14:05
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2010'	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2010'	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:15:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:15:47
Data point term sent to Coder	System	02 Oct 2020 16:15:09
User entered 'bilateral knee osteoarthritis'	Karol Moore (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2010'	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2010'	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:56:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:56:46
Data point term sent to Coder	System	02 Oct 2020 16:16:11
User entered 'RIGHT KNEE MENISCUS TEAR REpair' reason for change: Data Entry Error	Karol Moore (b) (4)	02 Oct 2020 16:15:19
Data point term sent to Coder	System	02 Oct 2020 16:15:10
User entered 'right knee meniscus tear reapri'	Karol Moore (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:16:43
Data point term sent to Coder	System	02 Oct 2020 16:16:11
User entered 'right knee meniscus tear'	Karol Moore (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2009'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2009'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2009'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2017'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2017'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:50
Data point term sent to Coder	System	02 Oct 2020 16:17:11
User entered 'left rotator cuff repair'	Karol Moore (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:50
Data point term sent to Coder	System	02 Oct 2020 16:17:20
User entered 'left rotator cuff tear'	Karol Moore (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2002'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2002'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2002'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2012'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2012'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:51
Data point term sent to Coder	System	02 Oct 2020 16:18:22
User entered 'obstructive sleep apnea'	Karol Moore (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2014'	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2014'	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:18:51
Data point term sent to Coder	System	02 Oct 2020 16:18:22
User entered 'bilateral hearing loss'	Karol Moore (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2018'	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2018'	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Elbow sprain - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 07:47:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 07:47:18
Data point term sent to Coder	System	02 Oct 2020 16:19:24
User entered 'left elbow strain'	Karol Moore (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'un Jan 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'Jan 2019'	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '2019'	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered empty.	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '14:35'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '08 Sep 2020 14:35'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '69.5' in	(b) (4)	02 Oct 2020 16:20:55
DataPoint set to visible.	Karol Moore (b) (4)	08 Sep 2020 20:58:05
	(b) (4)	
	System	

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '219' lb	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55
DataPoint set to visible.	(b) (4) System	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered '31.94364'	System	02 Oct 2020 16:20:55
DataPoint set to visible.	System	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'kg/m2'	System	02 Oct 2020 16:20:55
DataPoint set to visible.	System	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'bpm'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'breaths/min'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'mmHg'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User entered 'mmHg'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21

US3312548

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:21:35

US3312548

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:21:35

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '0'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:18:21
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:10:11
User entered '8 Sep 2020'	Karol Moore (b) (4)	10 Nov 2020 17:10:11
	(b) (4)	
	Christa Estrada (b) (4)	08 Sep 2020 20:58:19
	(b) (4)	

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'VISIT1'	System	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '190313'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	Christa Estrada (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:25:32
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:42:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:42:32

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	02 Oct 2020 16:27:03
	(b) (4)	

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '14:35'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered '08 Sep 2020 14:35'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'bpm'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'breaths/min'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '140'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '85'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '16:25'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered '08 Sep 2020 16:25'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '98.4' F	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'bpm'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'breaths/min'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '152'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '92'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:32

US3312548

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:32

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:12:10
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Heather Barker (b) (4)	21 Oct 2020 18:36:36
' answered with 'updated' (Site from DM).	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	21 Oct 2020 18:36:27
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	14 Oct 2020 15:38:22
' (Site from DM).		
User entered '8 Sep 2020'	Christa Estrada (b) (4)	08 Sep 2020 20:59:02
	(b) (4)	

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '15:50'	(b) (4) Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered '08 Sep 2020 15:50'	System	21 Oct 2020 18:36:27
User entered '8 Sep 2020 15:50'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'ONCE'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '15:19'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered '08 Sep 2020 15:19'	System	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '15:10'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered '08 Sep 2020 15:10'	System	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered empty.	System	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:29:17

US3312548

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'I'	System	02 Oct 2020 16:29:17

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:32:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9749d837-7bac-4260-99db-6456a64af13b'	System	08 Sep 2020 21:33:19
User entered 'Yes (Y)'	System	08 Sep 2020 21:33:19

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:02', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9749d837-7bac-4260-99db-6456a64af13b'	System	08 Sep 2020 21:33:19
User entered '98.4'	System	08 Sep 2020 21:33:19

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:07', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9749d837-7bac-4260-99db-6456a64af13b'	System	08 Sep 2020 21:33:19
User entered 'No (N)'	System	08 Sep 2020 21:33:19

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:12', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9749d837-7bac-4260-99db-6456a64af13b'	System	08 Sep 2020 21:33:19
User entered '08 Sep 2020 16:33'	System	08 Sep 2020 21:33:19

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 18:40'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:24:31', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '1ed730dd-3fd3-42e3-8c85-ec700c19be49'	System	09 Sep 2020 01:25:01
User entered 'Yes (Y)'	System	09 Sep 2020 01:25:01

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:24:38', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '1ed730dd-3fd3-42e3-8c85-ec700c19be49'	System	09 Sep 2020 01:25:01
User entered '98.7'	System	09 Sep 2020 01:25:01

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:24:48', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '1ed730dd-3fd3-42e3-8c85-ec700c19be49'	System	09 Sep 2020 01:25:01
User entered 'No (N)'	System	09 Sep 2020 01:25:01

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:24:53', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '1ed730dd-3fd3-42e3-8c85-ec700c19be49'	System	09 Sep 2020 01:25:01
User entered '08 Sep 2020 20:24'	System	09 Sep 2020 01:25:01

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 19:35'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 2'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:16:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '941a7276-9139-42ad-8df0-e46966b98514'	System	09 Sep 2020 17:17:00
User entered 'Yes (Y)'	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:16:43', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '941a7276-9139-42ad-8df0-e46966b98514' User entered '97.6'	System	09 Sep 2020 17:17:00
	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:16:48', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '941a7276-9139-42ad-8df0-e46966b98514'	System	09 Sep 2020 17:17:00
User entered 'No (N)'	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:16:54', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '941a7276-9139-42ad-8df0-e46966b98514' User entered '09 Sep 2020 12:16'	System	09 Sep 2020 17:17:00
	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 3'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:10:37', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd10a6ba8-1a76-42b5-a470-489a5e715a73'	System	10 Sep 2020 18:10:59
User entered 'Yes (Y)'	System	10 Sep 2020 18:10:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:10:44', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd10a6ba8-1a76-42b5-a470-489a5e715a73'	System	10 Sep 2020 18:10:59
User entered '98.1'	System	10 Sep 2020 18:10:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:10:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd10a6ba8-1a76-42b5-a470-489a5e715a73'	System	10 Sep 2020 18:10:59
User entered 'No (N)'	System	10 Sep 2020 18:10:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:10:56', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd10a6ba8-1a76-42b5-a470-489a5e715a73'	System	10 Sep 2020 18:10:59
User entered '10 Sep 2020 13:10'	System	10 Sep 2020 18:10:59

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 4'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:25', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '2489a287-49a4-4378-868e-326fe065d1c0'	System	11 Sep 2020 17:47:00
User entered 'Yes (Y)'	System	11 Sep 2020 17:47:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:33', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '2489a287-49a4-4378-868e-326fe065d1c0'	System	11 Sep 2020 17:47:00
User entered '96.8'	System	11 Sep 2020 17:47:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:39', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '2489a287-49a4-4378-868e-326fe065d1c0'	System	11 Sep 2020 17:47:00
User entered 'No (N)'	System	11 Sep 2020 17:47:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:43', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '2489a287-49a4-4378-868e-326fe065d1c0'	System	11 Sep 2020 17:47:00
User entered '11 Sep 2020 12:46'	System	11 Sep 2020 17:47:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 5'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:01', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e613ef5c-f06d-4c33-b4b6-00d85a87a070'	System	12 Sep 2020 20:08:30
User entered 'Yes (Y)'	System	12 Sep 2020 20:08:30

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:17', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e613ef5c-f06d-4c33-b4b6-00d85a87a070'	System	12 Sep 2020 20:08:30
User entered '98.9'	System	12 Sep 2020 20:08:30

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:21', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e613ef5c-f06d-4c33-b4b6-00d85a87a070'	System	12 Sep 2020 20:08:30
User entered 'No (N)'	System	12 Sep 2020 20:08:30

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:27', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e613ef5c-f06d-4c33-b4b6-00d85a87a070'	System	12 Sep 2020 20:08:30
User entered '12 Sep 2020 15:08'	System	12 Sep 2020 20:08:30

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 6'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:28:19', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a4c044d2-252b-4c1e-823d-4e60ff40ebb7'	System	13 Sep 2020 22:28:36
User entered 'Yes (Y)'	System	13 Sep 2020 22:28:36

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:28:24', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a4c044d2-252b-4c1e-823d-4e60ff40ebb7'	System	13 Sep 2020 22:28:36
User entered '97.6'	System	13 Sep 2020 22:28:36

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:28:28', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a4c044d2-252b-4c1e-823d-4e60ff40ebb7'	System	13 Sep 2020 22:28:36
User entered 'No (N)'	System	13 Sep 2020 22:28:36

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:28:31', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a4c044d2-252b-4c1e-823d-4e60ff40ebb7'	System	13 Sep 2020 22:28:36
User entered '13 Sep 2020 17:28'	System	13 Sep 2020 22:28:36

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 7'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:05', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'eb5dc890-c405-4398-a0cb-d0ecbfd786cf'	System	14 Sep 2020 18:57:23
User entered 'Yes (Y)'	System	14 Sep 2020 18:57:23

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:12', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'eb5dc890-c405-4398-a0cb-d0ecbfd786cf'	System	14 Sep 2020 18:57:23
User entered '97.3'	System	14 Sep 2020 18:57:23

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:16', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'eb5dc890-c405-4398-a0cb-d0ecbfd786cf'	System	14 Sep 2020 18:57:23
User entered 'No (N)'	System	14 Sep 2020 18:57:23

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:19', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'eb5dc890-c405-4398-a0cb-d0ecbfd786cf'	System	14 Sep 2020 18:57:23
User entered '14 Sep 2020 13:57'	System	14 Sep 2020 18:57:23

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:31', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'c1784969-bf17-4a34-afdc-561a5324446d'	System	08 Sep 2020 21:33:54
User entered 'None (1)'	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:35', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'c1784969-bf17-4a34-afdc-561a5324446d'	System	08 Sep 2020 21:33:54
User entered 'No (N)'	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:39', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'c1784969-bf17-4a34-afdc-561a5324446d'	System	08 Sep 2020 21:33:54
User entered 'No (N)'	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:44', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'c1784969-bf17-4a34-afdc-561a5324446d'	System	08 Sep 2020 21:33:54
User entered 'None (1)'	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'c1784969-bf17-4a34-afdc-561a5324446d'	System	08 Sep 2020 21:33:54
User entered '08 Sep 2020 16:33'	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 18:40'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:06', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a2634758-4484-485e-95e7-7ec877dde566'	System	09 Sep 2020 01:25:37
User entered 'None (1)'	System	09 Sep 2020 01:25:37

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:10', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a2634758-4484-485e-95e7-7ec877dde566'	System	09 Sep 2020 01:25:37
User entered 'No (N)'	System	09 Sep 2020 01:25:37

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:15', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a2634758-4484-485e-95e7-7ec877dde566'	System	09 Sep 2020 01:25:37
User entered 'No (N)'	System	09 Sep 2020 01:25:37

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:20', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a2634758-4484-485e-95e7-7ec877dde566'	System	09 Sep 2020 01:25:37
User entered 'None (1)'	System	09 Sep 2020 01:25:37

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:26', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'a2634758-4484-485e-95e7-7ec877dde566'	System	09 Sep 2020 01:25:37
User entered '08 Sep 2020 20:25'	System	09 Sep 2020 01:25:37

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 19:35'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 2'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:11', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '04676761-a92b-4a2c-b553-42306936c326'	System	09 Sep 2020 17:17:39
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 17:17:39

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:16', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '04676761-a92b-4a2c-b553-42306936c326'	System	09 Sep 2020 17:17:39
User entered 'No (N)'	System	09 Sep 2020 17:17:39

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:20', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '04676761-a92b-4a2c-b553-42306936c326'	System	09 Sep 2020 17:17:39
User entered 'No (N)'	System	09 Sep 2020 17:17:39

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:26', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '04676761-a92b-4a2c-b553-42306936c326'	System	09 Sep 2020 17:17:39
User entered 'None (1)'	System	09 Sep 2020 17:17:39

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:33', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '04676761-a92b-4a2c-b553-42306936c326'	System	09 Sep 2020 17:17:39
User entered '09 Sep 2020 12:17'	System	09 Sep 2020 17:17:39

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 3'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:06', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '5c786fce-99e6-4877-88b1-0417f4fd78fd'	System	10 Sep 2020 18:11:26
User entered 'None (1)'	System	10 Sep 2020 18:11:26

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:09', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '5c786fce-99e6-4877-88b1-0417f4fd78fd'	System	10 Sep 2020 18:11:26
User entered 'No (N)'	System	10 Sep 2020 18:11:26

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:13', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '5c786fce-99e6-4877-88b1-0417f4fd78fd'	System	10 Sep 2020 18:11:26
User entered 'No (N)'	System	10 Sep 2020 18:11:26

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:18', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '5c786fce-99e6-4877-88b1-0417f4fd78fd'	System	10 Sep 2020 18:11:26
User entered 'None (1)'	System	10 Sep 2020 18:11:26

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:22', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '5c786fce-99e6-4877-88b1-0417f4fd78fd'	System	10 Sep 2020 18:11:26
User entered '10 Sep 2020 13:11'	System	10 Sep 2020 18:11:26

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 4'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6756d1bc-8498-468f-ade6-ab490ee4e4c2'	System	11 Sep 2020 17:47:20
User entered 'None (1)'	System	11 Sep 2020 17:47:20

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:52', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6756d1bc-8498-468f-ade6-ab490ee4e4c2'	System	11 Sep 2020 17:47:20
User entered 'No (N)'	System	11 Sep 2020 17:47:20

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:46:56', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6756d1bc-8498-468f-ade6-ab490ee4e4c2'	System	11 Sep 2020 17:47:20
User entered 'No (N)'	System	11 Sep 2020 17:47:20

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6756d1bc-8498-468f-ade6-ab490ee4e4c2'	System	11 Sep 2020 17:47:20
User entered 'None (1)'	System	11 Sep 2020 17:47:20

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:04', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6756d1bc-8498-468f-ade6-ab490ee4e4c2'	System	11 Sep 2020 17:47:20
User entered '11 Sep 2020 12:47'	System	11 Sep 2020 17:47:20

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 5'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:34', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e9a2949d-585a-4476-9b9b-d78a0af8a0ad'	System	12 Sep 2020 20:08:51
User entered 'None (1)'	System	12 Sep 2020 20:08:51

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:37', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e9a2949d-585a-4476-9b9b-d78a0af8a0ad'	System	12 Sep 2020 20:08:51
User entered 'No (N)'	System	12 Sep 2020 20:08:51

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:40', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e9a2949d-585a-4476-9b9b-d78a0af8a0ad'	System	12 Sep 2020 20:08:51
User entered 'No (N)'	System	12 Sep 2020 20:08:51

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:42', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e9a2949d-585a-4476-9b9b-d78a0af8a0ad'	System	12 Sep 2020 20:08:51
User entered 'None (1)'	System	12 Sep 2020 20:08:51

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:46', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e9a2949d-585a-4476-9b9b-d78a0af8a0ad'	System	12 Sep 2020 20:08:51
User entered '12 Sep 2020 15:08'	System	12 Sep 2020 20:08:51

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 6'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:10', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '87140f6f-061c-4950-9a86-54b44c89a132'	System	13 Sep 2020 22:29:31
User entered 'None (1)'	System	13 Sep 2020 22:29:31

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:14', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '87140f6f-061c-4950-9a86-54b44c89a132'	System	13 Sep 2020 22:29:31
User entered 'No (N)'	System	13 Sep 2020 22:29:31

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:18', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '87140f6f-061c-4950-9a86-54b44c89a132'	System	13 Sep 2020 22:29:31
User entered 'No (N)'	System	13 Sep 2020 22:29:31

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:23', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '87140f6f-061c-4950-9a86-54b44c89a132'	System	13 Sep 2020 22:29:31
User entered 'None (1)'	System	13 Sep 2020 22:29:31

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:26', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '87140f6f-061c-4950-9a86-54b44c89a132'	System	13 Sep 2020 22:29:31
User entered '13 Sep 2020 17:29'	System	13 Sep 2020 22:29:31

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 7'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:39', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '15999881-964a-4302-997e-82045d33ee3e'	System	14 Sep 2020 18:58:03
User entered 'None (1)'	System	14 Sep 2020 18:58:03

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:43', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '15999881-964a-4302-997e-82045d33ee3e'	System	14 Sep 2020 18:58:03
User entered 'No (N)'	System	14 Sep 2020 18:58:03

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:47', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '15999881-964a-4302-997e-82045d33ee3e'	System	14 Sep 2020 18:58:03
User entered 'No (N)'	System	14 Sep 2020 18:58:03

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:51', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '15999881-964a-4302-997e-82045d33ee3e'	System	14 Sep 2020 18:58:03
User entered 'None (1)'	System	14 Sep 2020 18:58:03

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:57:55', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '15999881-964a-4302-997e-82045d33ee3e'	System	14 Sep 2020 18:58:03
User entered '14 Sep 2020 13:57'	System	14 Sep 2020 18:58:03

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:33:58', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:03', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:07', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:11', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:13', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'None (0)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:20', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '1dbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered 'No (N)'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T16:34:25', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ldbef48a-6e3b-4bc2-b589-618b3ffa59ca'	System	08 Sep 2020 21:34:31
User entered '08 Sep 2020 16:34'	System	08 Sep 2020 21:34:31

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 18:40'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:35', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:38', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:42', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:47', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:50', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:25:52', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'None (0)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:26:01', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered 'No (N)'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-08T20:26:06', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '738c4b73-1a47-4c1b-8d57-374def4e15b7'	System	09 Sep 2020 01:26:11
User entered '08 Sep 2020 20:26'	System	09 Sep 2020 01:26:11

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '08 Sep 2020 19:35'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 2'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:41', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:46', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:52', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:54', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:17:57', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'None (0)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:18:03', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered 'No (N)'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-09T12:18:06', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9b7da2db-7883-498b-8392-98fea134c413'	System	09 Sep 2020 17:18:13
User entered '09 Sep 2020 12:18'	System	09 Sep 2020 17:18:13

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 3'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:30', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:33', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:39', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:42', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:44', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'None (0)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:48', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered 'No (N)'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-10T13:11:58', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'd2a9fd68-bcb5-4906-92f0-9f3c4691dd44'	System	10 Sep 2020 18:12:05
User entered '10 Sep 2020 13:11'	System	10 Sep 2020 18:12:05

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 4'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:10', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:12', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:14', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:17', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:19', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:21', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'None (0)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:25', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered 'No (N)'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-11T12:47:29', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '48e8f133-6e37-431f-a532-0dff825185cc'	System	11 Sep 2020 17:47:34
User entered '11 Sep 2020 12:47'	System	11 Sep 2020 17:47:34

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 5'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:53', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:55', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:08:58', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:09:01', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:09:03', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:09:05', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'None (0)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:09:09', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered 'No (N)'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-12T15:09:12', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '34f93fa2-237e-4986-8118-c0bb39796425'	System	12 Sep 2020 20:09:17
User entered '12 Sep 2020 15:09'	System	12 Sep 2020 20:09:17

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 6'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:39', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:40', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:43', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:45', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:47', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'None (0)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:51', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered 'No (N)'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-13T17:29:54', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'e5443931-8187-483a-9213-1c27ba6a3b23'	System	13 Sep 2020 22:29:58
User entered '13 Sep 2020 17:29'	System	13 Sep 2020 22:29:58

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 7'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:06', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'None (0)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:08', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'None (0)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:10', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'None (0)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:13', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f' User entered 'None (0)'	System	14 Sep 2020 18:58:29
	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:15', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'None (0)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:17', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'None (0)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:19', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f'	System	14 Sep 2020 18:58:29
User entered 'No (N)'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-09-14T13:58:26', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '145a42b0-9602-4fa2-9f60-6fa3e538bb8f' User entered '14 Sep 2020 13:58'	System	14 Sep 2020 18:58:29
	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:59:02

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:18:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '16 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4)	02 Oct 2020 16:30:54
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:58

US3312548

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'I'	System	02 Oct 2020 16:30:58

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '22 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:00

US3312548

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:03:48
User entered 'I'	System	02 Oct 2020 16:32:00

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4)	02 Oct 2020 16:32:15
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:18

US3312548

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:09:45
User entered 'I'	System	02 Oct 2020 16:32:18

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'VISIT2'	System	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:23

US3312548

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:23

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	12 Oct 2020 22:37:37
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 22:37:37
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	12 Oct 2020 22:37:30
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered empty.	System	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:40:36

US3312548

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'I'	System	12 Oct 2020 15:40:36

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:03

US3312548

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'I'	System	12 Oct 2020 22:38:03

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:38:15

US3312548

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'I'	System	12 Oct 2020 22:38:15

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'occurred during convalescent period.'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:08

US3312548

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'I'	System	16 Nov 2020 22:19:08

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered 'VISIT3'	System	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '08:54'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered '10 Nov 2020 08:54'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '70'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered 'bpm'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered 'breaths/min'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '144'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered 'mmHg'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:23:38
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS. ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 22:20:34
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Nov 2020 22:19:54
User entered '102'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered 'mmHg'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:46

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:46

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered '09:09'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered '10 Nov 2020 09:09'	System	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:22:06

US3312548

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:42
User entered '1'	System	16 Nov 2020 22:22:06

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 64'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-10T09:16:08', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '65e62cce-898e-4558-b337-12c9d12c06c7'	System	10 Nov 2020 15:16:24
User entered 'No (N)'	System	10 Nov 2020 15:16:24

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-10T09:16:13', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '65e62cce-898e-4558-b337-12c9d12c06c7'	System	10 Nov 2020 15:16:24
User entered 'No (N)'	System	10 Nov 2020 15:16:24

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-10T09:16:18', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '65e62cce-898e-4558-b337-12c9d12c06c7'	System	10 Nov 2020 15:16:24
User entered '10 Nov 2020 09:16:18'	System	10 Nov 2020 15:16:24

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered 'Day 71'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-16T07:58:24', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '79afd3e1-cf58-4ef0-867c-500c8ca29d44'	System	16 Nov 2020 13:58:47
User entered 'No (N)'	System	16 Nov 2020 13:58:47

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-16T07:58:33', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '79afd3e1-cf58-4ef0-867c-500c8ca29d44'	System	16 Nov 2020 13:58:47
User entered 'No (N)'	System	16 Nov 2020 13:58:47

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-16T07:58:43', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '79afd3e1-cf58-4ef0-867c-500c8ca29d44'	System	16 Nov 2020 13:58:47
User entered '16 Nov 2020 07:58:43'	System	16 Nov 2020 13:58:47

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 20:59:02

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:03:31
Data entry locked.	System	08 Sep 2020 20:59:02
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 20:59:02

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2020-11-22T08:47:33', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3bd0c583-b63b-4553-bcb4-f4d9ffea3ee6'	System	22 Nov 2020 14:47:56
User entered 'No (N)'	System	22 Nov 2020 14:47:56

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2020-11-22T08:47:46', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3bd0c583-b63b-4553-bcb4-f4d9ffea3ee6'	System	22 Nov 2020 14:47:56
User entered 'No (N)'	System	22 Nov 2020 14:47:56

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-22T08:47:52', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3bd0c583-b63b-4553-bcb4-f4d9ffea3ee6'	System	22 Nov 2020 14:47:56
User entered '22 Nov 2020 08:47:52'	System	22 Nov 2020 14:47:56

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2020-11-26T10:02:48', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '13f98151-8aa2-4dbb-bb83-43c43f15eadb'	System	26 Nov 2020 16:03:09
User entered 'No (N)'	System	26 Nov 2020 16:03:09

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2020-11-26T10:02:56', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '13f98151-8aa2-4dbb-bb83-43c43f15eadb'	System	26 Nov 2020 16:03:09
User entered 'No (N)'	System	26 Nov 2020 16:03:09

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-11-26T10:03:01', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '13f98151-8aa2-4dbb-bb83-43c43f15eadb' User entered '26 Nov 2020 10:03:01'	System	26 Nov 2020 16:03:09
	System	26 Nov 2020 16:03:09

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2020-12-10T08:46:56', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '7e718886-a5f2-49a7-bffc-4f496eb5423d'	System	10 Dec 2020 14:47:14
User entered 'No (N)'	System	10 Dec 2020 14:47:14

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2020-12-10T08:47:04', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '7e718886-a5f2-49a7-bffc-4f496eb5423d'	System	10 Dec 2020 14:47:14
User entered 'No (N)'	System	10 Dec 2020 14:47:14

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-12-10T08:47:09', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '7e718886-a5f2-49a7-bffc-4f496eb5423d'	System	10 Dec 2020 14:47:14
User entered '10 Dec 2020 08:47:09'	System	10 Dec 2020 14:47:14

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2020-12-17T07:26:09', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '96435cdf-b8db-4d8b-84f3-a7bb44730942'	System	17 Dec 2020 13:26:53
User entered 'No (N)'	System	17 Dec 2020 13:26:53

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2020-12-17T07:26:45', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '96435cdf-b8db-4d8b-84f3-a7bb44730942'	System	17 Dec 2020 13:26:53
User entered 'No (N)'	System	17 Dec 2020 13:26:53

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-12-17T07:26:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '96435cdf-b8db-4d8b-84f3-a7bb44730942'	System	17 Dec 2020 13:26:53
User entered '17 Dec 2020 07:26:49'	System	17 Dec 2020 13:26:53

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2020-12-24T07:41:42', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6dd82486-912e-482e-9297-6311b53d0e59'	System	24 Dec 2020 13:41:57
User entered 'No (N)'	System	24 Dec 2020 13:41:57

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2020-12-24T07:41:49', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6dd82486-912e-482e-9297-6311b53d0e59'	System	24 Dec 2020 13:41:57
User entered 'No (N)'	System	24 Dec 2020 13:41:57

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2020-12-24T07:41:53', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6dd82486-912e-482e-9297-6311b53d0e59' User entered '24 Dec 2020 07:41:53'	System	24 Dec 2020 13:41:57
	System	24 Dec 2020 13:41:57

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-01-01T17:59:17', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '947af5db-c7b2-40a3-949d-6847e42c53c4'	System	01 Jan 2021 23:59:32
User entered 'No (N)'	System	01 Jan 2021 23:59:32

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-01-01T17:59:21', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '947af5db-c7b2-40a3-949d-6847e42c53c4'	System	01 Jan 2021 23:59:32
User entered 'No (N)'	System	01 Jan 2021 23:59:32

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-01-01T17:59:27', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '947af5db-c7b2-40a3-949d-6847e42c53c4'	System	01 Jan 2021 23:59:32
User entered '01 Jan 2021 17:59:27'	System	01 Jan 2021 23:59:32

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-01-07T06:04:57', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '4c7cb38c-e96f-4c77-b90d-152499902418'	System	07 Jan 2021 12:05:11
User entered 'No (N)'	System	07 Jan 2021 12:05:11

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-01-07T06:05:03', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '4c7cb38c-e96f-4c77-b90d-152499902418'	System	07 Jan 2021 12:05:11
User entered 'No (N)'	System	07 Jan 2021 12:05:11

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-01-07T06:05:07', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '4c7cb38c-e96f-4c77-b90d-152499902418'	System	07 Jan 2021 12:05:11
User entered '07 Jan 2021 06:05:07'	System	07 Jan 2021 12:05:11

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-01-18T15:57:29', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '52b30d99-3f33-41ff-8d60-09c69b424c45'	System	18 Jan 2021 21:57:41
User entered 'No (N)'	System	18 Jan 2021 21:57:41

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-01-18T15:57:32', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '52b30d99-3f33-41ff-8d60-09c69b424c45'	System	18 Jan 2021 21:57:41
User entered 'No (N)'	System	18 Jan 2021 21:57:41

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-01-18T15:57:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '52b30d99-3f33-41ff-8d60-09c69b424c45'	System	18 Jan 2021 21:57:41
User entered '18 Jan 2021 15:57:36'	System	18 Jan 2021 21:57:41

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-01-21T08:31:30', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '43396b39-89ab-4a1e-9957-2af2bd164ef8'	System	21 Jan 2021 14:31:45
User entered 'No (N)'	System	21 Jan 2021 14:31:45

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-01-21T08:31:34', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '43396b39-89ab-4a1e-9957-2af2bd164ef8'	System	21 Jan 2021 14:31:45
User entered 'No (N)'	System	21 Jan 2021 14:31:45

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-01-21T08:31:37', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '43396b39-89ab-4a1e-9957-2af2bd164ef8' User entered '21 Jan 2021 08:31:37'	System	21 Jan 2021 14:31:45
	System	21 Jan 2021 14:31:45

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-01-28T02:12:34', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'aa801d8b-f1f8-48f6-99da-be56f622daa6'	System	28 Jan 2021 08:12:48
User entered 'No (N)'	System	28 Jan 2021 08:12:48

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-01-28T02:12:36', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'aa801d8b-f1f8-48f6-99da-be56f622daa6'	System	28 Jan 2021 08:12:48
User entered 'No (N)'	System	28 Jan 2021 08:12:48

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-01-28T02:12:40', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'aa801d8b-f1f8-48f6-99da-be56f622daa6'	System	28 Jan 2021 08:12:48
User entered '28 Jan 2021 02:12:40'	System	28 Jan 2021 08:12:48

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-02-04T09:23:54', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ea3ebe1a-02b9-4b30-b405-ea0c2b7dd821'	System	04 Feb 2021 15:24:04
User entered 'No (N)'	System	04 Feb 2021 15:24:04

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-02-04T09:23:56', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ea3ebe1a-02b9-4b30-b405-ea0c2b7dd821'	System	04 Feb 2021 15:24:04
User entered 'No (N)'	System	04 Feb 2021 15:24:04

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-02-04T09:23:59', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'ea3ebe1a-02b9-4b30-b405-ea0c2b7dd821'	System	04 Feb 2021 15:24:04
User entered '04 Feb 2021 09:23:59'	System	04 Feb 2021 15:24:04

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-02-11T09:38:20', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '645a4385-d3a9-456e-b4fe-148a55879d5a'	System	11 Feb 2021 15:38:30
User entered 'No (N)'	System	11 Feb 2021 15:38:30

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-02-11T09:38:15', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '645a4385-d3a9-456e-b4fe-148a55879d5a'	System	11 Feb 2021 15:38:30
User entered 'No (N)'	System	11 Feb 2021 15:38:30

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-02-11T09:38:25', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '645a4385-d3a9-456e-b4fe-148a55879d5a'	System	11 Feb 2021 15:38:30
User entered '11 Feb 2021 09:38:25'	System	11 Feb 2021 15:38:30

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-02-18T07:37:55', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '27af17b7-cd8b-470d-832a-3a37f28ca1cc'	System	18 Feb 2021 13:38:19
User entered 'No (N)'	System	18 Feb 2021 13:38:19

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-02-18T07:38:03', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '27af17b7-cd8b-470d-832a-3a37f28ca1cc'	System	18 Feb 2021 13:38:19
User entered 'No (N)'	System	18 Feb 2021 13:38:19

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-02-18T07:38:12', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '27af17b7-cd8b-470d-832a-3a37f28ca1cc'	System	18 Feb 2021 13:38:19
User entered '18 Feb 2021 07:38:12'	System	18 Feb 2021 13:38:19

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-02-25T08:12:46-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '25e53968-01d8-49e4-ac5c-382464a96b62' User entered 'No (N)'	System	26 Feb 2021 01:21:10
	System	26 Feb 2021 01:21:10

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-02-25T08:12:49-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '25e53968-01d8-49e4-ac5c-382464a96b62'	System	26 Feb 2021 01:21:10
User entered 'No (N)'	System	26 Feb 2021 01:21:10

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-02-25T08:12:51-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '25e53968-01d8-49e4-ac5c-382464a96b62'	System	26 Feb 2021 01:21:10
User entered '25 Feb 2021 08:12:51'	System	26 Feb 2021 01:21:10

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-03-04T07:50:53-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9dd3055b-7ea5-432c-8156-a13c5665696c'	System	04 Mar 2021 13:51:05
User entered 'No (N)'	System	04 Mar 2021 13:51:05

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-03-04T07:50:56-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9dd3055b-7ea5-432c-8156-a13c5665696c'	System	04 Mar 2021 13:51:05
User entered 'No (N)'	System	04 Mar 2021 13:51:05

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-04T07:51:00-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '9dd3055b-7ea5-432c-8156-a13c5665696c'	System	04 Mar 2021 13:51:05
User entered '04 Mar 2021 07:51:00'	System	04 Mar 2021 13:51:05

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-03-12T19:42:30-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6054bac6-4ae4-4d6c-a961-bf7756059cea'	System	13 Mar 2021 01:42:51
User entered 'No (N)'	System	13 Mar 2021 01:42:51

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-03-12T19:42:33-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6054bac6-4ae4-4d6c-a961-bf7756059cea'	System	13 Mar 2021 01:42:51
User entered 'No (N)'	System	13 Mar 2021 01:42:51

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-12T19:42:47-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '6054bac6-4ae4-4d6c-a961-bf7756059cea' User entered '12 Mar 2021 19:42:47'	System	13 Mar 2021 01:42:51
	System	13 Mar 2021 01:42:51

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-03-18T08:06:53-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3be0775b-152b-4a26-8aa2-3ca69a16a5cb'	System	18 Mar 2021 13:07:02
User entered 'No (N)'	System	18 Mar 2021 13:07:02

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-03-18T08:06:55-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3be0775b-152b-4a26-8aa2-3ca69a16a5cb'	System	18 Mar 2021 13:07:02
User entered 'No (N)'	System	18 Mar 2021 13:07:02

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-18T08:06:58-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '3be0775b-152b-4a26-8aa2-3ca69a16a5cb' User entered '18 Mar 2021 08:06:58'	System	18 Mar 2021 13:07:02
	System	18 Mar 2021 13:07:02

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-03-25T13:18:52-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b4ec84cf-a284-47e5-a7d8-e4a51e0c8b94'	System	25 Mar 2021 18:19:06
User entered 'No (N)'	System	25 Mar 2021 18:19:06

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-03-25T13:18:56-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b4ec84cf-a284-47e5-a7d8-e4a51e0c8b94'	System	25 Mar 2021 18:19:06
User entered 'No (N)'	System	25 Mar 2021 18:19:06

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-25T13:18:59-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b4ec84cf-a284-47e5-a7d8-e4a51e0c8b94'	System	25 Mar 2021 18:19:06
User entered '25 Mar 2021 13:18:59'	System	25 Mar 2021 18:19:06

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-04-01T02:00:25-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '407feb05-7a8b-4080-9d16-114198ac9535'	System	01 Apr 2021 07:00:47
User entered 'No (N)'	System	01 Apr 2021 07:00:47

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-04-01T02:00:36-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '407feb05-7a8b-4080-9d16-114198ac9535'	System	01 Apr 2021 07:00:47
User entered 'No (N)'	System	01 Apr 2021 07:00:47

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-04-01T02:00:40-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '407feb05-7a8b-4080-9d16-114198ac9535'	System	01 Apr 2021 07:00:47
User entered '01 Apr 2021 02:00:40'	System	01 Apr 2021 07:00:47

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-04-09T21:02:00-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '676f0aca-5559-451f-b955-5a69de9e312f' User entered 'No (N)'	System	10 Apr 2021 02:04:26
	System	10 Apr 2021 02:04:26

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-04-09T21:02:05-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '676f0aca-5559-451f-b955-5a69de9e312f' User entered 'No (N)'	System	10 Apr 2021 02:04:26

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-04-09T21:02:11-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '676f0aca-5559-451f-b955-5a69de9e312f' User entered '09 Apr 2021 21:02:11'	System	10 Apr 2021 02:04:26
	System	10 Apr 2021 02:04:26

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-04-16T11:48:25-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '316bb188-301f-4598-a4d0-7e548b95f824' User entered 'No (N)'	System	16 Apr 2021 16:48:43
	System	16 Apr 2021 16:48:43

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-04-16T11:48:27-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '316bb188-301f-4598-a4d0-7e548b95f824'	System	16 Apr 2021 16:48:43
User entered 'No (N)'	System	16 Apr 2021 16:48:43

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-04-16T11:48:30-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '316bb188-301f-4598-a4d0-7e548b95f824'	System	16 Apr 2021 16:48:43
User entered '16 Apr 2021 11:48:30'	System	16 Apr 2021 16:48:43

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-04-23T12:38:20-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b435110a-87f0-4839-9501-e32cc09adb8c' User entered 'No (N)'	System	23 Apr 2021 17:38:35
	System	23 Apr 2021 17:38:35

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-04-23T12:38:23-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b435110a-87f0-4839-9501-e32cc09adb8c'	System	23 Apr 2021 17:38:35
User entered 'No (N)'	System	23 Apr 2021 17:38:35

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-04-23T12:38:26-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b435110a-87f0-4839-9501-e32cc09adb8c'	System	23 Apr 2021 17:38:35
User entered '23 Apr 2021 12:38:26'	System	23 Apr 2021 17:38:35

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[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 (35f4621905efa025)', Time: '2021-04-29T08:01:08-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b75dd956-7486-4d3c-bbcc-409df3b2e9c4'	System	29 Apr 2021 13:01:49
User entered 'No (N)'	System	29 Apr 2021 13:01:49

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

Have you been exposed to someone with 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 (35f4621905efa025)', Time: '2021-04-29T08:01:11-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b75dd956-7486-4d3c-bbcc-409df3b2e9c4'	System	29 Apr 2021 13:01:49
User entered 'No (N)'	System	29 Apr 2021 13:01:49

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-04-29T08:01:14-05:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: 'b75dd956-7486-4d3c-bbcc-409df3b2e9c4'	System	29 Apr 2021 13:01:49
User entered '29 Apr 2021 08:01:14'	System	29 Apr 2021 13:01:49

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:20:18

US3312548

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:18:49

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 17:45:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-04T07:51:26-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '4657e45c-5f83-489e-a253-42a4e6348dff'	System	04 Mar 2021 13:51:51
User entered 'No (N)'	System	04 Mar 2021 13:51:51

US3312548

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:18:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35f4621905efa025)', Time: '2021-03-04T07:51:31-06:00', User OID: 'PatientReportedOutcome (US3312548)', ODM File OID: '4657e45c-5f83-489e-a253-42a4e6348dff' User entered '04 Mar 2021 07:51:31'	System	04 Mar 2021 13:51:51
	System	04 Mar 2021 13:51:51

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:50:15

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:50:15

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:50:15

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:50:15

US3312548

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:50:18

US3312548

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:56:40
User entered 'I'	System	02 Dec 2020 14:50:18

US3312548

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 15:47:55

US3312548

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered '04 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 15:47:55

US3312548

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 15:47:55

US3312548

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 15:47:55

US3312548

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 15:48:17

US3312548

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User entered 'I'	System	05 Jan 2021 15:48:17

US3312548

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 14:55:55

US3312548

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered '01 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 14:55:55

US3312548

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 14:55:55

US3312548

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 14:55:55

US3312548

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 14:55:46

US3312548

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User entered 'I'	System	02 Feb 2021 14:55:46

US3312548

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 16:30:37

US3312548

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered '02 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 16:30:37

US3312548

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Mar 2021 16:30:37

US3312548

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 16:30:37

US3312548

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 16:30:14

US3312548

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:23:47
User entered 'I'	System	03 Mar 2021 16:30:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered 'VISIT4'	System	22 Mar 2021 19:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered empty.	System	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered empty.	System	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered empty.	System	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered empty.	System	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered empty.	System	31 Mar 2021 15:06:14

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43

US3312548

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43

US3312548

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:36

US3312548

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:36

US3312548

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:53

US3312548

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:53

US3312548

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '10:39'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:53

US3312548

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered '22 Mar 2021 10:39'	System	22 Mar 2021 19:06:53

US3312548

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:06:59

US3312548

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:20:43
User entered 'I'	System	22 Mar 2021 19:06:59

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:18:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:51:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:18:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:51:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07:53'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:18:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:03
User entered '07 Oct 2020 07:53'	System	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:18:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:51:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:18:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:51:33
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	18 Dec 2020 16:57:42
User entered empty.	System	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 20:29:38
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 20:29:38
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '04 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	18 Dec 2020 16:57:42
User entered empty.	System	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 20:29:38
User entered '04 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:51

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	18 Dec 2020 16:57:42
User entered empty.	System	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	18 Dec 2020 16:57:42
User entered empty.	System	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 16:57:42
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	21 Oct 2020 18:25:26
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:25:26
User entered 'Day 9 (Day 9)'	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	12 Oct 2020 20:38:46
User entered '09 Oct 2020' reason for change: Data Entry Error	System	12 Oct 2020 20:38:46
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 20:36:46
User entered '09 Dec 2020'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	21 Oct 2020 18:25:26
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	21 Oct 2020 17:35:15
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	21 Oct 2020 18:25:26
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	21 Oct 2020 17:35:15
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 18:27:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:27:43
User entered '12 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 17:35:15
User entered empty.	System	21 Oct 2020 17:35:15
	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:27:43
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:27:43
User entered empty.	System	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 11 (Day 11)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '13 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.6' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:54:32
Query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 18:41:39
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 18:41:29
User opened query 'Per CDM: Most of the assessments are not done, please consider adding missing data or if there is not data available then please consider selecting each assessment as "Not Done". Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:59:37
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 18:42:07
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:28:44
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 12 (Day 12)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '14 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:29:39

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '97.4' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Mild (Mild)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:29:39
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 13 (Day 13)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '15 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '97.4' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:16
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 14 (Day 14)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '16 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:30:58

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.3' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:30:58
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 15 (Day 15)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '17 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.5' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:31:41
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 16 (Day 16)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:33:35

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '18 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '100'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:33:35

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.2' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:33:35
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'per CDM: please confirm symptom day for 19 Oct 2020, as day 13 also noted as 15 Oct 2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 11:34:31
Query 'per CDM: please confirm symptom day for 19 Oct 2020, as day 13 also noted as 15 Oct 2020' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:50:40
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 22:50:26
User opened query 'per CDM: please confirm symptom day for 19 Oct 2020, as day 13 also noted as 15 Oct 2020' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 08:08:43
User entered 'Day 13 (Day 13)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '19 Oct 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '97.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	21 Oct 2020 18:34:11
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:11
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Day 18 (Day 18)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 03NOV2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:07:56
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 03NOV2020. Please reconcile or clarify.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	10 Nov 2020 13:48:03
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 03NOV2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:13:40
User entered '20 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
User entered '%'	System	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.6' F	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:18:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:55:59
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 18:34:45
	(b) (4)	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:49

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

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[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 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:49

[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 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
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)	15 Oct 2020 18:02:06
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).	(b) (4), (b) (6)	12 Oct 2020 16:03:38
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	12 Oct 2020 16:02:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:49

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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[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 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:00:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:02:29

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:16
User entered 'I'	System	12 Oct 2020 16:02:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[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 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[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 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 16:03:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 16:03:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 16:03:25
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 16:03:15
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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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 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Form: Covid-19 Severity Assessment

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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 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[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 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:18:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:45
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:18:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:39:21

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 18:57:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 20:41:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:57:39
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 20:41:23
	(b) (4)	
	(b) (4), (b) (6)	

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 18:57:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 20:41:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:57:39
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 20:41:23
	(b) (4)	
	(b) (4), (b) (6)	

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:00:56
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED IN EDC' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:25:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:56:27
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 18:57:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 20:41:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 18:57:39
User entered empty.	Karol Moore (b) (4)	12 Oct 2020 20:41:23
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per CDM: it appears Day 28 occurred on 03NOV2020. Please complete Day 28 of the Saliva log' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:43:43
Query 'Per CDM: it appears Day 28 occurred on 03NOV2020. Please complete Day 28 of the Saliva log' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:22:23
User opened query 'Per CDM: it appears Day 28 occurred on 03NOV2020. Please complete Day 28 of the Saliva log' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:14:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 18:24:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 08:52:03
Query 'Data is required. Please complete.' answered with 'will update when completed' (Site from System).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:58:04
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:41:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:24:54
User entered '20 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 18:24:25
User entered empty.	(b) (4)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:18:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:18:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:22:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 08:52:06
Query 'Data is required. Please complete.' answered with 'will updated when completed' (Site from System).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:58:11
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:41:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:10:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:22:16
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:57
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:57
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:01:57
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered 'SICKD1'	System	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '12:35'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered '07 Oct 2020 12:35'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '69' in	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58
DataPoint set to visible.	System	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:38:52
User closed query 'Source documents 205 lbs. please review and update. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:38:49
Query 'Source documents 205 lbs. please review and update. ' answered with 'updated per source' (Site from CRA).	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:20:16
Signature has been broken.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:20:02
User entered '205' lb reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:20:02
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:36
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User opened query 'Source documents 205 lbs. please review and update. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:06:01
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 18:14:24
User entered '105' lb	(b) (4), (b) (6)	12 Oct 2020 20:39:58
DataPoint set to visible.	System	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '73'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered 'bpm'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered 'breaths/min'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '162'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered 'mmHg'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:06:31
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:27:35
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'noted as AE per protocol but NCS' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 20:40:22
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Oct 2020 20:39:58
User entered '107'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
User entered 'mmHg'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:40:34

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:15
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:40:34

US3312548

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:18:49

[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 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:40:43

US3312548

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:40:43

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 18:22:24
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:22:24
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[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 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:07:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Clinic (Clinic)'	Karol Moore (b) (4)	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'SICKD28'	System	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 18:23:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '09:16'	(b) (4)	06 Nov 2020 18:23:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered '03 Nov 2020 09:16'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	
DataPoint set to visible.	System	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	06 Nov 2020 18:23:30
DataPoint set to visible.	(b) (4) System	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '98.9' F	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4)	06 Nov 2020 18:23:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '87'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'bpm'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '16'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'breaths/min'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '139'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'mmHg'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:27
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '81'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:30
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
User entered 'mmHg'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 18:23:36

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:41
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:36
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:18:49

[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 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:57
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:23:47
	(b) (4)	

US3312548

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:18:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:09:57
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:47

US3312548

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

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:50:04

US3312548

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

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:50:04

US3312548

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

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:50:04

US3312548

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

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 14:50:04

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:50:29

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 09:01:39
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'Subject did not receive second dose ' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 14:49:18
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	13 Jan 2021 14:48:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:50:29

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:11:58
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:11:58
Comment added 'Subject did not receive second dose of placebo. Placebo entered in order to populate additional decisions visit pages.'	(b) (4), (b) (6)	13 Jan 2021 14:54:19
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:52:55
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '1'	System	13 Jan 2021 14:52:55
User entered empty.	System	13 Jan 2021 14:48:25

US3312548

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

Form: Unblinding

Generated On: 11 Aug 2021 22:18:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'I'	System	13 Jan 2021 14:52:55
User entered empty.	System	13 Jan 2021 14:48:25

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	13 Jan 2021 14:57:20
DataPoint set to visible.	System	13 Jan 2021 14:52:55

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	13 Jan 2021 14:57:20
DataPoint set to visible.	System	13 Jan 2021 14:52:55

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '13:32'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '12 Jan 2021 13:32'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '84'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'bpm'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '14'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'breaths/min'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '130'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '89'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	13 Jan 2021 14:57:20
DataPoint set to visible.	System	13 Jan 2021 14:52:55

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '15:01'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '12 Jan 2021 15:01'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '81'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'bpm'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '14'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'breaths/min'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '125'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '77'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:20

US3312548

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	13 Jan 2021 14:57:20

US3312548

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:30

US3312548

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:30

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mRNA-1273'	System	13 Jan 2021 14:57:43
DataPoint set to visible.	System	13 Jan 2021 14:52:55

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '14:30'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '12 Jan 2021 14:30'	System	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'ONCE'	System	13 Jan 2021 14:57:43

US3312548

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

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 14:57:43

US3312548

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:43

US3312548

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:43

US3312548

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12:52'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:43

US3312548

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '12 Jan 2021 12:52'	System	13 Jan 2021 14:49:43

US3312548

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:52

US3312548

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:52

US3312548

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '12:51'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:49:52

US3312548

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '12 Jan 2021 12:51'	System	13 Jan 2021 14:49:52

US3312548

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

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:01

US3312548

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

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'I'	System	22 Jan 2021 19:29:01

US3312548

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:22

US3312548

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:22

US3312548

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:22

US3312548

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:22

US3312548

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:26

US3312548

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'I'	System	22 Jan 2021 19:29:26

US3312548

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '1'	System	22 Jan 2021 19:29:26
DataPoint set to visible.	System	22 Jan 2021 19:29:26

US3312548

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:09

US3312548

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:09

US3312548

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:09

US3312548

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'OLD29'	System	11 Feb 2021 20:50:09

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '13:15'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '09 Feb 2021 13:15'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '81'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'bpm'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'breaths/min'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '138'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '88'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '14:21'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '09 Feb 2021 14:21'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'bpm'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'breaths/min'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '133'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '79'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mmHg'	System	11 Feb 2021 20:50:59

US3312548

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:06

US3312548

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:06

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'mRNA-1273'	System	11 Feb 2021 20:51:18
DataPoint set to visible.	System	22 Jan 2021 19:29:26

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '13:50'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '09 Feb 2021 13:50'	System	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'ONCE'	System	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 20:51:18

US3312548

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:50:00

US3312548

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'I'	System	11 Feb 2021 20:50:00

US3312548

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:38:25

US3312548

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:38:25

US3312548

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:38:25

US3312548

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:38:25

US3312548

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:38:30

US3312548

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'I'	System	18 Feb 2021 15:38:30

US3312548

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:22

US3312548

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:22

US3312548

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:22

US3312548

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered 'OLD57'	System	22 Mar 2021 19:08:22

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User closed query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 01:26:51
Query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	02 Apr 2021 14:22:00
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 14:24:27
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered empty.	System	22 Mar 2021 19:08:31

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05

US3312548

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05

US3312548

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:44

US3312548

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:44

US3312548

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:53

US3312548

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:53

US3312548

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '10:39'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:08:53

US3312548

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:05
User entered '22 Mar 2021 10:39'	System	22 Mar 2021 19:08:53

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '08 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '16:30'	(b) (4)	02 Oct 2020 16:28:16
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User entered '08 Sep 2020 16:30'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4)	02 Oct 2020 16:28:16
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User entered 'bpm'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User entered 'breaths/min'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '151'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User entered 'mmHg'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '91'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43
User entered 'mmHg'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:43

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:18:49

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '09:00'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User entered '10 Nov 2020 09:00'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User entered 'bpm'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User entered 'breaths/min'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '137'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User entered 'mmHg'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '91'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08
User entered 'mmHg'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:08:08

US3312548

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:18:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:10
User closed query 'Source documents low hemoglobin AE on 17Feb2021. Please add AE to log line. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:43:02
Query 'Source documents low hemoglobin AE on 17Feb2021. Please add AE to log line. ' answered with 'updated' (Site from CRA).	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:18:07
User opened query 'Source documents low hemoglobin AE on 17Feb2021. Please add AE to log line. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:22:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:18
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 16:06:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:51:05

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:25
User entered 'USA-US300-2020-mRNA-1273-P301000003'	System	13 Oct 2020 15:19:20
User entered 'New'	(b) (4), (b) (6)	13 Oct 2020 15:19:20

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
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)	12 Oct 2020 22:04:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 22:04:35
Data point term sent to Coder	System	12 Oct 2020 22:02:59
User entered 'symptomatic covid 19'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	21 Oct 2020 17:30:17
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 17:30:17
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	21 Oct 2020 17:29:41
User entered 'Yes (Y)'	System	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:59:48
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'end date provided' (Site from Safety).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:30:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 17:30:08
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Oct 2020 17:30:08
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	21 Oct 2020 17:29:41
User entered '15 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:29:41
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:48:25
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 12:42:10
User closed query "'Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:22:41
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'correct as entered, due to SARS Covid 19' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 18:40:54
Query "'Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:40:09
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	26 Oct 2020 18:39:44

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query "'Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or if subject withdrew only IP then please consider completing "Dosing discontinuation" form under "End of Study" folder or clarify otherwise. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:54:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'Per CDM: Concomitant Medication is checked, however no Medication has been added with the indication of 'symptomatic Covid 19'. Please review and update or comment accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:51:24
Query 'Per CDM: Concomitant Medication is checked, however no Medication has been added with the indication of 'symptomatic Covid 19'. Please review and update or comment accordingly. ' answered with 'updated on conmed pages' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:32:06
User opened query 'Per CDM: Concomitant Medication is checked, however no Medication has been added with the indication of 'symptomatic Covid 19'. Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:55:52
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
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)	22 Oct 2020 20:59:36
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).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:49:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:30:08
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:48:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:18:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is recorded in the ConProc eCRF. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:27:43
Query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is recorded in the ConProc eCRF. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:09:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is recorded in the ConProc eCRF. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:46:28
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAS ROUTINE CARDIAC STRESS TEST SCHEDULED. Please confirm if this was performed; and if so, ensure that this is captured in the appropriate eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:46:28
Query 'Per DM CLR: SAE Narrative = SUBJECT HAS ROUTINE CARDIAC STRESS TEST SCHEDULED. Please confirm if this was performed; and if so, ensure that this is captured in the appropriate eCRF. Otherwise, clarify. ' answered with 'updated-done every 5 yrs routinely, not due to symptoms...test results normal' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:19:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS ROUTINE CARDIAC STRESS TEST SCHEDULED WHICH REQUIRED PRE EXAM COVID TEST WHICH RESULTED IN POSITIVE RESULT. SUBJECT CALLED SITE SAME DAY RESULT GIVEN AND SWAB DONE AT SITE WHICH WAS POSITIVE. SUBJECT HAD NOT RECOGNIZED SYMPTOMS UNTIL AFTER TEST RESULTS GIVEN-THEN REPORTED TO SITE. POSITIVE RESULTS RECEIVED AT SITE TODAY. SUBJECT IS FEELING BETTER WITH ONLY MILD FATIGUE AND COUGH ONGOING., O2 SATS REMAINED HIGH 90S-100%, TOOK OTC MEDS ONLY. DID NOT SEEK ADDITIONAL MEDICAL CARE. Update: 10Nov2020: subject has cardiac stress test done which was normal, done routinely every 5 yrs, not due to symptoms.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:19:03
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAS ROUTINE CARDIAC STRESS TEST SCHEDULED. Please confirm if this was performed; and if so, ensure that this is captured in the appropriate eCRF. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:45:46
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:50:22
User closed query 'PV Query: Please provide the results of the immunologic assessment.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:50:12
User closed query 'PV Query: Please provide the results of the saliva test.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:50:00
User closed query 'PV Query: Please provide the date the pre exam COVID test was received.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:49:45
Query 'PV Query: Please provide the results of the immunologic assessment.' answered with 'NA per protocol' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 18:47:37
Query 'PV Query: Please provide the date the pre exam COVID test was received.' answered with '07oct2020' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 18:47:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of the saliva test.' answered with 'Day 3, Day 7, Day 9 all positive; day 14=negative, Day 21 pending' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 18:47:04
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'no known exposure, risk factor of 65 yrs of age' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 18:46:23
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:59:28
User closed query 'PV Query: Please provide the OTC medication the subject was taking. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:59:16
Query 'PV Query: Please provide the OTC medication the subject was taking. If unknown, please state so.' answered with 'updated to conmed page' (Site from Safety).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:52:39
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'added and updated' (Site from Safety).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:32:56
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:49:14
User opened query 'PV Query: Please provide the results of the immunologic assessment.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:49:06
User opened query 'PV Query: Please provide the OTC medication the subject was taking. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:48:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:48:06
User opened query 'PV Query: Please provide the results of the saliva test.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:47:34
User opened query 'PV Query: Please provide the date the pre exam COVID test was received.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:47:25
User entered 'Subject has routine cardiac stress test scheduled which required pre exam covid test which resulted in positive result. subject called site same day result given and swab done at site which was positive. Subject had not recognized symptoms until after test results given-then reported to site. Positive results received at site today. Subject is feeling better with only mild fatigue and cough ongoing., O2 sats remained high 90s-100%, Took otc meds only. Did not seek additional medical care.'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:18:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 22:02:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 18:35:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 18:35:24
Data point term sent to Coder	System	06 Nov 2020 18:33:58
User entered 'EXACERBATION OF HYPERTENSION'	Karol Moore (b) (4)	06 Nov 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 19:38:39
	(b) (4)	
User entered '16 Oct 2020'	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
User entered empty.	System	06 Nov 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 19:38:39
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 19:38:39
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
User entered empty.	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 06:27:18
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'REVIEWED AND UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:08:21
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:08:14
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:45:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'I'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	06 Nov 2020 19:38:39
Data Entry Error	Karol Moore (b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:21:15
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:06:51
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	06 Nov 2020 18:33:11
	(b) (4)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
User entered '0'	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51
User entered 'I'	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:18:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:10:51

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User coded data point as SOC: Investigations, HLG: Haematology investigations (incl blood groups), HLT: Red blood cell analyses, PT: Haemoglobin decreased, LLT: Hemoglobin low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 23:19:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 23:19:37
Data point term sent to Coder	System	20 Apr 2021 23:19:11
User entered 'low hemoglobin'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '17 Feb 2021'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'I'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered '0'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Apr 2021 18:15:47
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:42:47
User entered empty.	Karol Moore (b) (4) (b) (4)	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 23:19:06

US3312548

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:18:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 23:19:06

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:18:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per ETRTR: According to AE "COVID-19" page, medication was dosed for COVID. Please add Medication dosing details for COVID-19 within ConMeds page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:57:59
User closed query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:08:49
Query 'Per ETRTR: According to AE "COVID-19" page, medication was dosed for COVID. Please add Medication dosing details for COVID-19 within ConMeds page, thanks.' answered with 'medication added' (Site from CRA).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 19:04:43
Query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' answered with 'reviewed and updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 19:04:36
User opened query 'Per ETRTR: According to AE "COVID-19" page, medication was dosed for COVID. Please add Medication dosing details for COVID-19 within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 23:02:47
User opened query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:19:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:38:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 18:42:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:42:33
Data point term sent to Coder	System	21 Oct 2020 18:41:22
User entered 'methylphenidate'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4)	21 Oct 2020 18:40:38
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Attention deficit disorder'	Karol Moore (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '10'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:52:26
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User entered '1'	System	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User entered '1'	System	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:29
User entered '804 (804)'	System	21 Oct 2020 18:40:38

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 18:42:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:42:33
Data point term sent to Coder User entered 'lisinopril'	System Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:23 21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4)	21 Oct 2020 18:41:13
	Karol Moore (b) (4)	
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'hypertension'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '5'	Karol Moore (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:34:45
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:41:13
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:34:45
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:41:13
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User entered '1'	System	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User entered '1'	System	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:32
User entered '804 (804)'	System	21 Oct 2020 18:41:13

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 18:43:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:43:37
Data point term sent to Coder	System	21 Oct 2020 18:42:27
User entered 'rosuvastatin'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:42:15

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'un UNK 2017'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:42:15
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:42:15

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:42:15

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 18:42:15

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:36
Data point term sent to Coder	System	21 Oct 2020 18:43:28
User entered 'praluent pen'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per DM CLR: Please note, 75 mg/ml is a concentration/strength, rather than dosage. Please provide the actual dose for this medication (e.g., 75 mg, 150 mg, etc). Update the Dose and Dose Unit fields as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:12:54
Query 'Per DM CLR: Please note, 75 mg/ml is a concentration/strength, rather than dosage. Please provide the actual dose for this medication (e.g., 75 mg, 150 mg, etc). Update the Dose and Dose Unit fields as appropriate.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 19:19:41
' answered with 'UPDATED' (Site from DM).		
User opened query 'Per DM CLR: Please note, 75 mg/ml is a concentration/strength, rather than dosage. Please provide the actual dose for this medication (e.g., 75 mg, 150 mg, etc). Update the Dose and Dose Unit fields as appropriate. (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:23:31
User entered '75'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:19:29
	(b) (4)	
User entered 'Other (OTHER)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:19:29
	(b) (4)	
User entered 'mg/ml'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'other (OTHER)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'once every 14 days'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'un Jan 2020'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 18:45:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:45:42
Data point term sent to Coder	System	21 Oct 2020 18:44:29
User entered 'aspirin'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:44:11

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'health maintenance'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '81'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'un UNK 2012'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:44:11
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:44:11

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:44:11

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 18:44:11

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 18:46:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:46:50
Data point term sent to Coder	System	21 Oct 2020 18:45:30
User entered 'fish oil'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'prophylaxis'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:21:25
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:20:21
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:20:15
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:23:15
User entered '1'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:20:15
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'un UNK 2012'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:44:36
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 18:44:36

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Oct 2020 23:16:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:16:44
Data point term sent to Coder	System	21 Oct 2020 18:46:36
User entered 'Continuous positive airway pressure'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'obstructive sleep apnea'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Other (OTHER)'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'nasal mask'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'other (OTHER)'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'nightly'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'un UNK 2014'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	21 Oct 2020 18:45:43
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: ACETAMINOPHEN;PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:31:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:31:30
Data point term sent to Coder	System	21 Oct 2020 18:47:41
User entered 'acetaminophen 325mg/phenylephrine 5mg'	Karol Moore (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'symptomatic covid-19'	Karol Moore (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'tablet (TABLET)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'as needed (PRN)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '03 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '07 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User entered empty.	System	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User entered empty.	System	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:37
User entered empty.	System	21 Oct 2020 18:47:02

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Nov 2020 08:29:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:29:28
Data point term sent to Coder	System	06 Nov 2020 18:36:00
User entered 'LISINOPRIL 20MG/Hydrochlorothiazide 12.5MG'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:35:55

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'EXACERBATION OF HYPERTENSION'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'tablet (TABLET)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '17 Oct 2020'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Nov 2020 18:35:55
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:35:55

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:35:55

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:35:55

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: DRUGS FOR TREATMENT OF HYPERKALEMIA AND HYPERPHOSPHATEMIA, PRODUCT: FERRIC CITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Jan 2021 15:14:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:14:00
Data point term sent to Coder	System	13 Jan 2021 15:04:15
User entered 'ferric citrate'	(b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:03:40

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Jan 2021 15:06:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:06:00
Data point term sent to Coder	System	13 Jan 2021 15:05:15
User entered 'Meloxicam '	(b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:05:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 15:05:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 15:05:04
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:04:58
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '7.5'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:04:58

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
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.	(b) (4) Coder Import (b) (4)	13 Jan 2021 15:07:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 15:07:01
Data point term sent to Coder	System	13 Jan 2021 15:06:18
User entered 'Acetaminophen'	(b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '325'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:18:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:05:51

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:18:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:10
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 21:09:36
User entered 'No (N)'	Karol Moore (b) (4)	22 Oct 2020 11:56:59
	(b) (4)	
	(b) (4), (b) (6)	

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:18:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered '22 Oct 2020'	Karol Moore (b) (4)	19 Nov 2020 21:10:26
	(b) (4)	

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:18:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered 'CARDIAC STRESS TEST'	Karol Moore (b) (4)	19 Nov 2020 21:10:26
	(b) (4)	

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 13:43:48
Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Dec 2020 19:00:27
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 19:00:06
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 18:59:31
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	17 Dec 2020 18:59:31
User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:05:37
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:10:26

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:18:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4)	17 Dec 2020 19:00:06
	(b) (4)	
User entered 'PROPHYLAXIS'	Karol Moore (b) (4)	19 Nov 2020 21:10:26
	(b) (4)	

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:18:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:24:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:00:43

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:18:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:24:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Left knee arthroplasty'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:00:43

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:18:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:24:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:00:43

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:18:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:24:24
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:00:43

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:49

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:39:44

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User closed query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 00:04:43
Query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' answered with 'SUBJECT IS NOT RECIEVING FURTHER DOSING, BUT AGREES TO CONTINUE FOR SAFETY.' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:52:48
User opened query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 13:18:58
Un-reviewed for Data Management.	(b) (4), (b) (6)	01 Nov 2020 13:18:28
Reviewed for Data Management.	(b) (4), (b) (6)	01 Nov 2020 13:18:21
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	26 Oct 2020 18:39:44

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:24
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:39:44

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'USA-US300-2020-MRNA-1273-P301000003'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Carlos'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Fierro'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '16300 College Blvd'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Shawnee'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'KS'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '66219'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:00:47
User entered 'US'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 19:37:35
User entered '2'	System	22 Oct 2020 21:01:04
User entered '1'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'USA-US300-2020-MRNA-1273-P301000003'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Carlos'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Fierro'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '16300 College Blvd'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Shawnee'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'KS'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '66219'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:00:47
User entered 'US'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 19:37:35
User entered '2'	System	22 Oct 2020 21:01:04
User entered '1'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:18:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '13/Oct/2020 15:20'	(b) (4) System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:18:49

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:00:47
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'USA-US300-2020-MRNA-1273-P301000003'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Carlos'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Fierro'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '16300 College Blvd'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Shawnee'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'KS'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '66219'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:00:47
User entered 'US'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 19:37:35
User entered '2'	System	22 Oct 2020 21:01:04
User entered '1'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:18:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '22/Oct/2020 21:01'	(b) (4) System	22 Oct 2020 21:01:04

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:18:49

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:22
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 21:01:04

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'USA-US300-2020-MRNA-1273-P301000003'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'No (N)'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Carlos'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Fierro'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '16300 College Blvd'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'Shawnee'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered 'KS'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:19:55
User entered '66219'	System	13 Oct 2020 15:19:20

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 21:00:47
User entered 'US'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:18:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 19:37:35
User entered '2'	System	22 Oct 2020 21:01:04
User entered '1'	System	13 Oct 2020 15:20:01

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:18:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered '27/Oct/2020 15:37'	(b) (4) System	27 Oct 2020 19:37:35

US3312548

Folder: SAE USA-US300-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:18:49

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:16:02
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:14:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:37:35