

US3312548 (Prod: Johnson County Clin-Trials)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:55:22

All time stamps listed in this document are displayed in GMT

US3312548

Form: Participant Creation

Generated On: 26 Nov 2020 10:55:22

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	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

Generated On: 26 Nov 2020 10:55:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:22

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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 ☒

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

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

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input type="radio"/>

Folder OID	VISIT2
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US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 61
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: 26 Nov 2020 10:55:22

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

Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 68
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: 26 Nov 2020 10:55:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 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: 26 Nov 2020 10:55:22

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 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: 26 Nov 2020 10:55:22

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

Date and time of submission	
Patient Cloud Open Date & Time	26 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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

Date and time of submission	
Patient Cloud Open Date & Time	10 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: 26 Nov 2020 10:55:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

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

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 10:55:22

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

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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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 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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

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

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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	28 FEB 2022 23:59
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US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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

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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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 <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: 26 Nov 2020 10:55:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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: 26 Nov 2020 10:55:22

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 747

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

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

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

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

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

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

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 SEP 2022 00:01
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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="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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:55:22

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

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:55:22

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

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

Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2022 00:01
Patient Cloud Close Date & Time	14 NOV 2022 23:59

US3312548

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:22

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	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="radio"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input 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"/>
Day 33	<input type="checkbox"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

	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		
O2 Saturation Units		
Temperature		
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	306 of 2256	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

	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		
O2 Saturation Units		
Temperature		
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	310 of 2256	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

	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"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

	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	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	314 of 2256	

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

	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		
O2 Saturation Units		
Temperature		
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	318 of 2256	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

	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)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	322 of 2256	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

	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)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	326 of 2256	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	330 of 2256	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

	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 (8)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	334 of 2256	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	338 of 2256	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	342 of 2256	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 (11)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

	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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	346 of 2256	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	350 of 2256	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 (14)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Muscle Aches (Myalgia)	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Body Aches	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

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

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

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"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

	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"/>

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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 (18)

Generated On: 26 Nov 2020 10:55:22

[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"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

	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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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

Generated On: 26 Nov 2020 10:55:22

Date of Visit	07 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	07 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:22

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 _____

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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:22

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 _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:55:22

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 (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:55:22

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:35 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 12:35
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	105 lb
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	107 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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 _____

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

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: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:55:22

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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 _____

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

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: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:55:22

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
--------------------	--

US3312548

Folder: **Unscheduled 08 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:55:22**

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 09:00
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>)	137 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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

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)	

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:22

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

Yes ☒

No ☐

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

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	METHYLPHENIDATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ATTENTION DEFICIT DISORDER
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:22

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:22

	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"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	ROSUVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:22

	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"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	PRALUENT PEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	75
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:22

	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"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	HEALTH MAINTENANCE
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:22

	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"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	FISH OIL
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Indication	PROPHYLAXIS
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:22

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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 (7)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	CONTINUOUS POSITIVE AIRWAY PRESSURE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OBSTRUCTIVE SLEEP APNEA
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	NASAL MASK
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	NIGHTLY
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
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 (8)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	ACETAMINOPHEN 325MG/PHENYLEPRINE 5MG
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:22

	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"/>
<hr/>		
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"/>
<hr/>		
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"/>
<hr/>		
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)

Generated On: 26 Nov 2020 10:55:22

Name of Medication	LISINOPRIL 20MG/HYDROCHLOROTHIAZID E 12.5MG
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	EXACERBATION OF HYPERTENSION
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input checked="" type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/>

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:22

	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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:22

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:55:22

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
22 OCT 2020	CARDIAC STRESS TEST	Other	PROPHYLAXIS

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:22

Date of dosing discontinuation (dd MMM yyyy)

12 OCT 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3312548

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:55:22

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

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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)

Generated On: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3312548'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Sep 2020 19:04:43

US3312548

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Sep 2020 19:04:45

US3312548

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	08 Sep 2020 20:56:11

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 19:04:46

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Age](#)

Audit	User	Time (GMT)
User entered '65'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '65'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:22

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:56:42

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	10 Nov 2020 17:10:49
User entered '8 Sep 2020'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:57:59

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 19:04:45

US3312548

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:05

US3312548

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:10:32

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2000'	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:11:53

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:12:04

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:13:29

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2010'	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:14:45

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 16:15:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2009'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Oct 2020 16:16:07

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2012'	System	02 Oct 2020 16:16:31

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2002'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2012'	System	02 Oct 2020 16:17:08

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2014'	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:05

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLG: 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
	(b) (4)	

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:17

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un Jan 2019'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '2019'	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:18:42

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '14:35'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:35'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '69.5' in	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '219' lb	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:20:55

US3312548

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:21:35

US3312548

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:21:35

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

Other

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:22

[Specify](#)

Audit	User	Time (GMT)
User entered 'resides in community with ongoing person to person transmission'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:24:55

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	10 Nov 2020 17:10:11
User entered '8 Sep 2020'	Christa Estrada (b) (4)	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	08 Sep 2020 20:58:19

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '190313'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Sep 2020 20:29:29

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:58:31

US3312548

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4)	02 Oct 2020 16:25:32
	(b) (4)	
Amendment Manager: DataPoint set to visible.	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: 26 Nov 2020 10:55:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:22

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:55:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	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: 26 Nov 2020 10:55:22

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '14:35'	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	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: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	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: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	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: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	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: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:55:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '16:25'	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	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: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	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: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '152'	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: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '92'	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: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:27:03

US3312548

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:32

US3312548

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:32

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
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). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:12:10
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' answered with 'updated' (Site from DM).	Heather Barker (b) (4)	21 Oct 2020 18:36:36
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). ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 15:38:22
User entered '8 Sep 2020'	Christa Estrada (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '15:50'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 20:59:02

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:19'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:51

US3312548

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	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: 26 Nov 2020 10:55:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:10'	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:29:01

US3312548

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:29:17

US3312548

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:29:17

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	09 Sep 2020 17:17:00
User entered '97.6'	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 17:17:00
User entered '09 Sep 2020 12:16'	System	09 Sep 2020 17:17:00

US3312548

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '08 Sep 2020 16:33'	System	08 Sep 2020 21:33:54
	System	08 Sep 2020 21:33:54

US3312548

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: '1dbef48a-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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 10:55:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 18:58:29
User entered '14 Sep 2020 13:58'	System	14 Sep 2020 18:58:29

US3312548

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:55:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:54

US3312548

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:30:58

US3312548

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 16:30:58

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:31:55

US3312548

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:00

US3312548

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 16:32:00

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:15

US3312548

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:32:18

US3312548

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 16:32:18

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	12 Oct 2020 15:40:20

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:17

US3312548

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:23

US3312548

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:23

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

If No, reason not given

Audit	User	Time (GMT)
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).		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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:30

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:43

US3312548

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 22:37:49

US3312548

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:40:36

US3312548

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 15:40:36

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:37:58

US3312548

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:38:03

US3312548

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 22:38:03

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:38:11

US3312548

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:38:15

US3312548

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 22:38:15

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'occurred during convalescent period.'	(b) (4), (b) (6)	16 Nov 2020 22:25:56

US3312548

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:19:08

US3312548

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 22:19:08

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	16 Nov 2020 22:19:30

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '08:54'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '144'	(b) (4), (b) (6)	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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) (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 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).		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: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:19:54

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 22:21:46

US3312548

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:21:46

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:09'	(b) (4), (b) (6)	16 Nov 2020 22:21:59

US3312548

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:22:06

US3312548

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 22:22:06

US3312548

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[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: '2020-11-10T09:16:08', 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: 26 Nov 2020 10:55:22

Have you been exposed to someone with 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: '2020-11-10T09:16:13', 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: 26 Nov 2020 10:55:22

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[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: '2020-11-16T07:58:24', 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: 26 Nov 2020 10:55:22

Have you been exposed to someone with 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: '2020-11-16T07:58:33', 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: 26 Nov 2020 10:55:22

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

[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 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: 26 Nov 2020 10:55:22

[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 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: 26 Nov 2020 10:55:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:20:18
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 06:20:18

US3312548

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:22

[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 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: 26 Nov 2020 10:55:22

[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 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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

Have you been exposed to someone with 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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:22

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:22

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '07:53'	(b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:22

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:55:22

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:02:03

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:25:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:07

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:27:51

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:30:32

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '99.0' F	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:31:33

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change:	Karol Moore (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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.1' F	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:33:04

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 18:25:26
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Oct 2020 20:38:46
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 20:38:46
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	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: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.8' F	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:36:46

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 18:25:26
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 17:35:15
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:37:54

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 18:25:26
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 17:35:15
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 20:38:36

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Karol Moore (b) (4)	21 Oct 2020 18:27:43
Data Entry Error	(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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	21 Oct 2020 18:27:43
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:35:15
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:27:43
User entered empty.	Karol Moore (b) (4)	21 Oct 2020 17:35:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:28:44

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:29:39

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:16

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.3' F	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:30:58

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.5' F	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:31:41

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020'	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: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:33:35

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:33:35

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	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: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F	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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:11

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	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: 26 Nov 2020 10:55:22

[Date](#)

Audit	User	Time (GMT)
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) (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)	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)	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	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: 26 Nov 2020 10:55:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:55:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.6' F	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: 26 Nov 2020 10:55:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 10:55:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:34:45

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Date of Test](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:55:22

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:02:29

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:22

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Respiratory Rate](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Heart Rate](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[PaO2](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[ECMO?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Clinical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Radiographical Evidence](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 10:55:22

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:03:15

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:55:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	21 Oct 2020 18:57:39
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) (b) (4)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:55:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	21 Oct 2020 18:57:39
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) (b) (4)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	21 Oct 2020 18:57:39
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) (b) (4)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 18:57:39
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:55:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (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) (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)	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

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020' reason for change: Data Entry Error	Karol Moore (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), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:55:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Oct 2020 20:41:23

US3312548

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:55:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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)	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: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Oct 2020 20:39:11

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '12:35'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '69' in	(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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.0' F	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '162'	(b) (4), (b) (6)	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 20:39:58

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:40:34

US3312548

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(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: 26 Nov 2020 10:55:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:40:43

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '09:16'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:55:22

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 10:55:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 18:23:30

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:36

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:36

US3312548

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:55:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:47

US3312548

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:55:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:23:47

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	06 Nov 2020 18:22:24

US3312548

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	06 Nov 2020 18:22:24

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Visit Date](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:27:35

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '16:30'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '151'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '91'	Karol Moore (b) (4) (b) (4)	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 16:28:16

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Visit Date](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:55:22

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 22:21:06

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '09:00'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '137'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '91'	(b) (4), (b) (6)	16 Nov 2020 22:21:35

US3312548

Folder: Unscheduled 10 Nov 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 22:21:35

US3312548

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:51:05

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '03 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[AE start 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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 17:30:17
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	21 Oct 2020 17:30:17
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 17:29:41
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(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)	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)	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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	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
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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
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) (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 'I'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	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)	21 Oct 2020 18:49:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Narrative](#)

Audit	User	Time (GMT)
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) (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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[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

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:55:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 22:02:55

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:38:39
User entered '16 Oct 2020'	Karol Moore (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:38:39
User entered 'Yes (Y)'	Karol Moore (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:38:39
User entered empty.	Karol Moore (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

Severity

Audit	User	Time (GMT)
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) (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

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[None](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	06 Nov 2020 19:38:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 18:33:11

US3312548

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:55:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 18:33:11

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (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)	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)	21 Oct 2020 18:40:38
	(b) (4)	

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'Attention deficit disorder'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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 18:41:23
User entered 'lisinopril'	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 18:34:45
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 18:34:45
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
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) (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. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Nov 2020 19:19:41
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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:19:29
User entered 'Other (OTHER)'	Karol Moore (b) (4)	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	06 Nov 2020 19:19:29
User entered 'mg/ml'	Karol Moore (b) (4)	21 Oct 2020 18:43:28

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'once every 14 days'	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jan 2020'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'health maintenance'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2012'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'prophylaxis'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	(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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'obstructive sleep apnea'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'nasal mask'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'nightly'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 18:45:43

US3312548

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

Name of Medication

Audit	User	Time (GMT)
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) (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) (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/phenyleprine 5mg'	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'symptomatic covid-19'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 10:55:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'EXACERBATION OF HYPERTENSION'	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: 26 Nov 2020 10:55:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 10:55:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	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: 26 Nov 2020 10:55:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 10:55:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 10:55:22

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered '17 Oct 2020'	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: 26 Nov 2020 10:55:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 10:55:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:55:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 10:55:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:35:55

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Nov 2020 21:09:36
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 11:56:59

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:10:26

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CARDIAC STRESS TEST'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:10:26

US3312548

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:22

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:55:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered 'PROPHYLAXIS'	Karol Moore (b) (4) (b) (4)	19 Nov 2020 21:10:26

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:22

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 18:39:44

US3312548

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:22

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:55:22

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

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 10:55:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Oct/2020 15:20'	System	13 Oct 2020 15:20:01

US3312548

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '22/Oct/2020 21:01'	System	22 Oct 2020 21:01:04

US3312548

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

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:55:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:55:22

[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: 26 Nov 2020 10:55:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '27/Oct/2020 15:37'	System	27 Oct 2020 19:37:35

US3312548

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

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:55:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 19:37:35