

US3412126 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:26:14

All time stamps listed in this document are displayed in GMT

US3412126

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:14

[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 09:26:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	61
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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 09:26:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:14

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (2)

Generated On: 26 Nov 2020 09:26:14

Condition	OSTEOARTHRITIS HIPS AND SHOULDERS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (3)

Generated On: 26 Nov 2020 09:26:14

Condition	ANXIETY
Start date (dd MMM yyyy)	UN MAR 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 09:26:14

Condition	ALLERGIC RHINITIS - SEASONAL
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

Condition	CHRONIC BRONCHITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (7)

Generated On: 26 Nov 2020 09:26:14

Condition	FROZEN SHOULDER - BILATERAL
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (8)

Generated On: 26 Nov 2020 09:26:14

Condition	OSTEOPEROSIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:09 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:09
Height (<i>xxx.x</i>)	149.8 cm
Weight (<i>xxx.x</i>)	48.2 kg
BMI (<i>xxx.x</i>)	21.47946 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 09:26:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2010
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

(b) (6) FEMALE GOES TO GROCERY STORE, RESTAURANTS AND LIVES WITH ESSENTIAL WORKER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
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	LIVES IN HIGH RISK COUNTY

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100876

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

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 09:26:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:09
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 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 09:26:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	16:53 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:53
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

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 09:26:14

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)	04 AUG 2020
What was the treatment time? (00:00-23:59)	16:15 (24 HR)
Treatment Date and Time (derived)	04 AUG 2020 16:15
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 09:26:14

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	04 AUG 2020
Collection time (<i>00:00-23:59</i>)	15:40 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:14

Collection date (<i>dd MMM yyyy</i>)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:46	04 AUG 2020 15:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

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 09:26:14

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

98.1 °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 04 AUG 2020 16:59

PC Open Date & Time 04 AUG 2020 16:35

PC Close Date & Time 04 AUG 2020 19:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 AUG 2020 20:00

PC Close Date & Time 05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

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

100.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 AUG 2020 19:28

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

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	99.8 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	06 AUG 2020 19:33
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

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

100.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 AUG 2020 19:35

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:13

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

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

98.3 °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

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

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

99.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 AUG 2020 19:17

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

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

11 AUG 2020 19:39

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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

04 AUG 2020 17:01

PC Open Date & Time

04 AUG 2020 16:35

PC Close Date & Time

04 AUG 2020 19:05

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 20:00

PC Close Date & Time

05 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

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

05 AUG 2020 19:29

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

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

06 AUG 2020 19:33

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

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

07 AUG 2020 19:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

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

08 AUG 2020 19:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

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

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

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

10 AUG 2020 19:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 17:02
PC Open Date & Time	04 AUG 2020 16:35
PC Close Date & Time	04 AUG 2020 19:05

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 20:00

PC Close Date & Time

05 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	05 AUG 2020 19:30
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	06 AUG 2020 19:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	07 AUG 2020 19:37
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	08 AUG 2020 19:14
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	09 AUG 2020 19:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

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 ☒

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

Yes ☐	
PC Time stamp	10 AUG 2020 19:19
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

- 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 ☐

PC Time Stamp	11 AUG 2020 19:39
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 11 AUG 2020 19:39

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 AUG 2020 19:39

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	11 AUG 2020 19:40

PC Open Date & Time	11 AUG 2020 12:00

PC Close Date & Time	12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	11 AUG 2020 12:00

PC Close Date & Time	12 AUG 2020 11:59

PC Time stamp	11 AUG 2020 19:40

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 AUG 2020 19:40
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 10

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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 _____

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

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.

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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? _____

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:14

Was the sample collected?	Yes ☐
	No ☐

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

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:14

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3412126

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 117

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 173

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 222

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

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22 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

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09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

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16 SEP 2021 00:01

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20 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

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23 SEP 2021 00:01

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27 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

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04 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

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11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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11 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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25 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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20 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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27 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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 ☐ 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 ☐

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

Date of Contact	12 AUG 2020
Time of Contact	16:45
Date and Time of Contact (derived)	12 AUG 2020 16:45
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 AUG 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature	99.2 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	303 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	307 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	311 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	315 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	319 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	323 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	327 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	331 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	335 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	339 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	343 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	347 of 2283	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	351 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	355 of 2283	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

Date of Visit	12 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	12 AUG 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:26:14

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:26:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 AUG 2020
Day 5	Yes	16 AUG 2020
Day 7	Yes	18 AUG 2020
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:51 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 16:51
Height (<i>xxx.x</i>)	151 cm
Weight (<i>xxx.x</i>)	42 kg
Temperature (<i>xxx.x</i>)	99.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3412126

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:26:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 AUG 2020

US3412126

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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 _____

US3412126

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Were vital signs assessed?	Yes ☐
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

US3412126

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

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.

US3412126

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:26:14

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3412126

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

AEID	
Adverse event	UPPER RESPIRATORY INFECTION
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)	05 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	18 AUG 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	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

AEID	
Adverse event	RIB PAIN
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
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)	_____

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

AEID	USA-US061-2020-MRNA-1273-P30 1000004
Adverse event	PNEUMONIA
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 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	True
Hospital Admission Date (dd MMM yyyy)	23 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	01 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	374 of 2283

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

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

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

CALLED AND SPOKE TO
SUBJECT. SHE STATED SHE
WENT TO THE EMERGENCY
ROOM ON 23AUG2020 FOR RIB
PAIN FROM COUGHING. SHE
THOUGHT SHE BROKE A RIB
AND WANTED TO GET IT
WRAPPED. SHE STATED THAT
THEY DID A CHEST X-RAY AND
WAS DIAGNOSED WITH
PNEUMONIA AND ADMITTED
TO ST ELIZABETH HOSPITAL
FOR IV ANTIBIOTICS.
BRONCHOSCOPY WAS DONE
ON 25AUG2020 AND WAITING
FOR CULTURE RESULTS PER
SUBJECT. SHE SAID THEY WILL
DISCHARGE HER ONCE THEY
GET THE CULTURE RESULTS,
THEY CAN PUT HER ON THE
CORRECT ANTIBIOTICS FOR
HOME. SUBJECT STATED
FEELING MUCH BETTER AND
COUGH IS MUCH IMPROVED.

UPDATE: (b) (6)
FEMALE WITH CHEST PAIN. PT
HAS SEVERE, SHARP PAIN,
WORSE WITH COUGHING. PAIN
LOCATED ON RIGHT SIDE. PT
WAS GIVEN COVID 19 VACCINE
ON 8/4/20 AND HAD PAIN
STARTING THE FOLLOWING
DAY. FELT LIKE SHE HAD A
BROKEN RIB. SHE IS A
SMOKER. ASSOCIATED
SYMPTOMS INCLUDE POOR

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

APPETITE, DYSPNEA. PATIENT
WAS FOUND TO HAVE
CAVITARY PNA. NOW S/P
BRONCH. ID ON BOARD FOR
ABX MANAGMENT. PLAN FOR
LONG TERM IV ABX AT HOME (
ZOSYN) FOR AN ADDITIONAL 3
WEEKS. CRX WITH STABLE
EXTENSIVE R MIDDLE LOVE
INFILTRATE/ CONSOLIDATION
WITH KNOWN
INTRAPARENCHYMAL
ABSCCESS.

INITIAL LABS SHOWED
LEUCOCYTOSIS, BLOOD CX SO
FAR NGTD. CT SHOWED
MULTIFOCAL CONSOLIDATION
AND FLUID IN THE RML
CONCERNING FOR ABSCCESS.
SEEN BY PULMONOLOGY,
UNDERWENT BRONCHOSCOPY
WITH BAL ON 8/25/20. BAL
CULTURES AND CYTOLOGY
PENDING ID WAS CONSULTED
FOR ANTIBIOTIC
MANAGEMENT.

CULTURE RESULTS
STAPHYLOCOCCUS AUREUS
WAS NOT DETECTED
STREP PNEUMO ANTIGEN WAS
NOT DETECTED
LEGIONELLA ANTIGEN URINE
WAS NOT DETCTED
LOWER REPIRATORY CULTURE
NO WBC'S SEEN AND

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

NO ORGANISMS SEEN.

RESP VIRUS
RSP FAC SOURCE = BAL
INFLUENZA A-DFA NEGATIVE
INFLUENZA B-DFA NEGATIVE
PARAINFLUENZA 1- DFA
NEGATIVE
PARAINFLUENZA 2-DFA
NEGATIVE
PARAINFLUENZA 3- DFA
NEGATIVE
ADENOVIRUS- DFA NEGATIVE
RSV-DFA NEGATIVE
HUMAN METAPNEUMOVIRUS -
DFA NEGATIVE
FUNGUS CULTURE POSITIVE
GROWTH SPARSE GROWTH OF
YEAST, SUSPECT CANDIDA
SPECIES, POSSIBLE
REPARATORY TRACT COLON

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:14

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

Yes ☒

No ☐

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

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	OXYCODONE-ACETAMINOPHE N
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	CARTIA
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	CELEXA
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	DICLOFENAC
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	75
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	FUROSEMIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	TIZANIDINE HYDROCHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	CALCIUM CHLORIDE - 10%
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOPOROSIS
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	PROLIA
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOPOROSIS
Dose per administration	60
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	TWO TIMES PER YEAR Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	URI
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 AUG 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	GUAIFENESIN
Prophylaxis	Yes ☐ No ☒
Indication	SAR
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	PIPERACILLIN-TAZOBACTAM
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	3.375
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	01 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

Name of Medication OXYCODONE- ACEAMINOPHEN
(5/325MG TABLET)

Prophylaxis Yes ☐
No ☒

Indication OA

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		UN UNK 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	BENZONATATE
Prophylaxis	Yes ☐ No ☒
Indication	URI - UPPER RESPIRATORY INFECTION
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 18 AUG 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	FEVER
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		25 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

Name of Medication NASACORT - 55MCG

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 55

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		08 OCT 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	MOMETASONE - 50MCG
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN
Dose per administration	8
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:14

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:26:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 AUG 2020	PNEUMONIA (WITH A BRONCHOSCOPY WITH BAL DONE ON 25-AUG-2020)	Medical History	
22 AUG 2020	X-RAY CHEST (PA&LATERAL)	Adverse Event	
22 AUG 2020	X-RAY RIBS	Adverse Event	
22 AUG 2020	CT PULMONARY ANGIOGRAM	Adverse Event	
31 AUG 2020	SECOND XRAY CHEST (PA&LATERAL)	Adverse Event	
31 AUG 2020	PICC LINE INSERTION	Adverse Event	
23 AUG 2020	ECG'S DAILY FROM 23-AUG-2020 TO 30-AUG-2020	Adverse Event	

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:14

Date of dosing discontinuation (dd MMM yyyy)

18 NOV 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

PATIENTS DECISION TO NOT
COME IN FOR SECOND
INJECTION AND ALSO NOT
FOLLOWING ANY PROTOCOL
REQUIREMENTS

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:26:14

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 ☐

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	28/AUG/2020 13:09
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/SEP/2020 09:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/OCT/2020 16:53
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	27/OCT/2020 13:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:06
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/NOV/2020 01:29
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:26:14

SAEID	USA-US061-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:33
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

US3412126 (Prod: New Horizons Clinical Research)

US3412126

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:14

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3412126'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:19:42

US3412126

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:19:43

US3412126

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:19:44

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Age](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '61'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Black](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:14

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:19:43

US3412126

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:39:47

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

[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)	07 Aug 2020 14:42:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:42:09
Data point term sent to Coder	System	07 Aug 2020 14:41:08
User entered 'Hypertension'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2010'	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

[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 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:03:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:03:24
Data point term sent to Coder	System	07 Aug 2020 14:41:08
User entered 'Osteoarthritis Hips and shoulders'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014' reason for change:	Melissa Fuson (b) (4)	26 Oct 2020 18:13:07
Data Entry Error	(b) (4)	
User entered 'UN UNK 2015'	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	26 Oct 2020 18:13:07
User entered 'Jan 2015'	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2014'	System	26 Oct 2020 18:13:07
User entered '2015'	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:42:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:42:10
Data point term sent to Coder	System	07 Aug 2020 14:41:09
User entered 'Anxiety'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN Mar 2015' reason for change: Data	Melissa Fuson (b) (4)	26 Oct 2020 18:13:30
Entry Error	(b) (4)	
User entered 'UN Mar 2020'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Mar 2015'	System	26 Oct 2020 18:13:30
User entered 'Mar 2020'	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2015'	System	26 Oct 2020 18:13:30
User entered '2020'	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 15:32:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Oct 2020 15:32:34
Data point term sent to Coder	System	20 Oct 2020 15:31:53
User entered 'post menopausal'	Jacob sekinger (b) (4)	20 Oct 2020 15:31:00
	(b) (4)	

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2010'	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 17:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 17:11:35
Data point term sent to Coder	System	26 Oct 2020 17:02:58
User entered 'ALLERGIC RHINITIS - SEASONAL'	Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2019'	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 17:14:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 17:14:38
Data point term sent to Coder	System	26 Oct 2020 17:04:02
User entered 'CHRONIC BRONCHITIS'	Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2010'	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

[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: Periarthritis, LLT: Frozen shoulder - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:22:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:22:32
Data point term sent to Coder	System	26 Oct 2020 17:05:02
User entered 'FROZEN SHOULDER - BILATERAL'	Melissa Fuson (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:44:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:44:29
Data point term sent to Coder	System	26 Oct 2020 17:15:15
User entered 'OSTEOPEROSIS'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '2015'	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:09'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:09'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '149.8' cm	(b) (4), (b) (6)	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '48.2' kg	(b) (4), (b) (6)	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '21.47946'	System	16 Sep 2020 23:43:02
User entered '21.5'	System	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM, For Screening and V1D1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign V1D1 page. Please update accordingly else clarify. Thank you' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4)	23 Sep 2020 17:53:02
Query 'Per CDM, For Screening and V1D1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign V1D1 page. Please update accordingly else clarify. Thank you' answered with 'V1 WILL BE DONE ON A DIFFERENT DAY' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User opened query 'Per CDM, For Screening and V1D1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign V1D1 page. Please update accordingly else clarify. Thank you' (Site from DM). User entered '37.1' C	Mylene Asmar-Rios (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 19:19:56 31 Aug 2020 06:25:47 07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User entered '84'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User entered '114'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
User entered '74'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:42:42

US3412126

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:42:42

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:24:13
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4)	20 Oct 2020 15:31:09
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:05:30
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:26:14

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:22:45
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

[Specify](#)

Audit	User	Time (GMT)
User entered (b) (6) FEMALE GOES TO GROCERY STORE, RESTAURANTS AND LIVES WITH ESSENTIAL WORKER' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:22:45
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Sep 2020 19:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:14

[Specify](#)

Audit	User	Time (GMT)
User entered 'LIVES IN HIGH RISK COUNTY'	Mylene Asmar-Rios	22 Sep 2020 19:22:45
reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:04:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:04:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:54:16
User entered '100876' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

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)'	(b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:14

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:09' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:09'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Sep 2020 19:26:10
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Sep 2020 19:26:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '74' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6) (b) (4)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:14

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:12:21
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 14:45:19
User entered '16:53'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:53'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:44:01

US3412126

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:44:01

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '16:15'	(b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:40'	(b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:40'	System	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:14

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:46'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:46'	System	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:14

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 14:44:05

US3412126

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 14:44:05

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered 'Yes (Y)'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered '98.1'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered 'No (N)'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered '04 Aug 2020 16:59'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered 'Yes (Y)'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '100.6'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered 'Yes (Y)'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	01 Oct 2020 14:29:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:52', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	(b) (4)	
User entered '1'	System	05 Aug 2020 23:28:17
	System	05 Aug 2020 23:28:17
	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:52', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '0'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '05 Aug 2020 19:28'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered 'Yes (Y)'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '99.8'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:48', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered 'Yes (Y)'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted ' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	01 Oct 2020 14:33:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	(b) (4)	
User entered '1'	System	06 Aug 2020 23:33:12
	System	06 Aug 2020 23:33:12
	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '0'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '06 Aug 2020 19:33'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:14', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered 'Yes (Y)'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:21', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '100.4'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered 'Yes (Y)'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	01 Oct 2020 14:34:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	(b) (4)	
User entered '1'	System	07 Aug 2020 23:35:39
	System	07 Aug 2020 23:35:39
	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '0'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '07 Aug 2020 19:35'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered 'Yes (Y)'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:34', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered '99.5'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:39', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered 'No (N)'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered '08 Aug 2020 19:13'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:25:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered 'Yes (Y)'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered '98.3'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:05', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered 'No (N)'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered 'Yes (Y)'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:26', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '99.2'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered 'Yes (Y)'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient was contacted' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:47:40
User entered '1'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '0'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '10 Aug 2020 19:17'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:17:47
User entered 'Day 8'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:38:55', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered 'Yes (Y)'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered '98.1'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:06', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered 'No (N)'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-04T17:00:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'None (1)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'No (N)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'No (N)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-04T17:01:07', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'None (1)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:15', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered '04 Aug 2020 17:01'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-05T19:28:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:36', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'No (N)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'No (N)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-05T19:28:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'None (1)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered '05 Aug 2020 19:29'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-06T19:33:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:28', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'No (N)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'No (N)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-06T19:33:39', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'None (1)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered '06 Aug 2020 19:33'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-07T19:35:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'None (1)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'No (N)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'No (N)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-07T19:35:57', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'None (1)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered '07 Aug 2020 19:36'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-08T19:13:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'None (1)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'No (N)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:57', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'No (N)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-08T19:14:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'None (1)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered '08 Aug 2020 19:14'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-09T19:26:16', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'None (1)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'No (N)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'No (N)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-09T19:26:27', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'None (1)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-10T19:17:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'None (1)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'No (N)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'No (N)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-10T19:18:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'None (1)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:04', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered '10 Aug 2020 19:18'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'No interference with activity (1)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:40', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:58', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-04T17:02:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'No (N)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:02:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered '04 Aug 2020 17:02'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:59', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-05T19:30:08', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'No (N)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:30:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered '05 Aug 2020 19:30'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:17', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-06T19:34:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'No (N)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:41', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered '06 Aug 2020 19:34'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:59', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:19', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'None (0)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:29', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-07T19:37:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'No (N)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered '07 Aug 2020 19:37'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:13', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:17', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:26', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-08T19:14:29', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No (N)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered '08 Aug 2020 19:14'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:48', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:27:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-09T19:27:05', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No (N)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:27:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered '09 Aug 2020 19:27'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:15', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'Some interference with activity (2)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:04', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'None (0)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-10T19:19:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No (N)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered '10 Aug 2020 19:19'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd3e20896-30cf-4eda-8508-22222c7e3316'	System	11 Aug 2020 23:39:27
User entered 'None (0)'	System	11 Aug 2020 23:39:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:23', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd3e20896-30cf-4eda-8508-22222c7e3316'	System	11 Aug 2020 23:39:27
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:34', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '09de7434-6352-40e8-befb-088dee7f94e3'	System	11 Aug 2020 23:39:39
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '09de7434-6352-40e8-befb-088dee7f94e3'	System	11 Aug 2020 23:39:39
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 9'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:39:39
User entered 'Day 10'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '4800ddf5-7d27-4139-afe8-92c290507341'	System	11 Aug 2020 23:39:56
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '4800ddf5-7d27-4139-afe8-92c290507341'	System	11 Aug 2020 23:39:56
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 9'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:39:56
User entered 'Day 10'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7c2ff8cc-24db-41b2-928a-4adb9673cfca'	System	11 Aug 2020 23:40:05
User entered 'None (0)'	System	11 Aug 2020 23:40:05

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7c2ff8cc-24db-41b2-928a-4adb9673cfca'	System	11 Aug 2020 23:40:05
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:05

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:08', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c49c7b8d-93f9-4b87-9f44-a2fe97e4dc29'	System	11 Aug 2020 23:40:13
User entered 'None (0)'	System	11 Aug 2020 23:40:13

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:11', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c49c7b8d-93f9-4b87-9f44-a2fe97e4dc29'	System	11 Aug 2020 23:40:13
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:13

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

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 (3b033e968abc0106)', Time: '2020-08-11T19:40:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8299baef-d9f3-4d08-8ddb-2540336e2dd0'	System	11 Aug 2020 23:40:29
User entered 'No (N)'	System	11 Aug 2020 23:40:29

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:27', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8299baef-d9f3-4d08-8ddb-2540336e2dd0'	System	11 Aug 2020 23:40:29
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:29

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:17:47
User entered 'Day 9'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:39:39
User entered 'Day 10'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:39

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Aug 2020 20:11:29

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:11:29

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Subject still in illness period through this date - please change to no and delete all info on this page' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:47:02
Query 'Subject still in illness period through this date - please change to no and delete all info on this page' answered with 'subject was still in illness phase and this visit was not indicated' (Site from CRA).	Steven Anderson (b) (4)	18 Nov 2020 13:50:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 13:50:20
User opened query 'Subject still in illness period through this date - please change to no and delete all info on this page' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:58:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	18 Nov 2020 13:50:20
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	18 Nov 2020 13:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 23:48:01

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 23:48:01

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User closed query 'please confirm subject not continuing? If so, please complete end of study' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:02:22
Query 'please confirm subject not continuing? If so, please complete end of study' answered with 'PARTICIPANT IS CONTINUING BUT DUE TO AE'S THAT STARTED ON THEY ARE NOW GETTING SAFETY SICK CALL VISITS.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 20:10:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 20:07:23
User opened query 'please confirm subject not continuing? If so, please complete end of study' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:41:37
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 13:56:15

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:07:23
User entered empty.	System	18 Nov 2020 13:56:15

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'please add and complete illness visit folder (convalescent visit in add event)' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:05:23
Query 'please add and complete illness visit folder (convalescent visit in add event)' answered with 'illness visit added. ' (Site from CRA).	Jacob sekinger (b) (4)	06 Nov 2020 15:03:40
User opened query 'please add and complete illness visit folder (convalescent visit in add event)' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:00:05
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered '12 Aug 2020'	Melissa Fuson (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered '16:45'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:45'	System	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User closed query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:59:29
Query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' answered with 'UPDATED SYSTEM LOG FOR DAYS OF SYMPTON ONSET' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:17:59
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User opened query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:43:15
User closed query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:04:23
Query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' answered with 'updating ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:18:21
User opened query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:35:21
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:04
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:11
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:08
User entered '99.2' F	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:15
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:34
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:36
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:40
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:44
User entered 'None (None)'	Melissa Fuson (b) (4)	06 Oct 2020 19:07:27
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:00:13
User closed query 'please confirm - source only indicates lack of appetite' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:00:10
Query 'please confirm - source only indicates lack of appetite' answered with 'UPDATED' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 14:19:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 14:19:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User opened query 'please confirm - source only indicates lack of appetite' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:49:33
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:40
User entered 'None (None)'	Melissa Fuson (b) (4)	06 Oct 2020 19:07:27
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:44
User entered 'None (None)'	Melissa Fuson (b) (4)	06 Oct 2020 19:07:27
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 2 (Day 2)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:49:59
User entered '13 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:02
User entered '0'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:08
User entered '99'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:11
User entered '97.5' F	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:13
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:15
User entered 'Mild (Mild)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:22
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:26
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:28
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:30
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:31
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:33
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:35
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:36
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '14 Aug 2020'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 4 (Day 4)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '15 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 5 (Day 5)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '16 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.1' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 6 (Day 6)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '17 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4)	07 Oct 2020 21:37:35
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '18 Aug 2020'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '96'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

Fatigue

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Date](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:26:14

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:26:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:26:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:02:55
User closed query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:02:50
Query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' answered with 'UPDATED PER NEW COVID-19 ASSESSMENT' (Site from CRA).	Melissa Fuson (b) (4)	26 Oct 2020 18:10:30
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:42:36
User opened query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:36:41
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Oct 2020 19:09:50

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:48:28
User entered '13 Aug 2020'	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:46:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:54
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:46:54
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:48:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:48:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:48:28
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:48:28
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:26:14

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:26:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:14

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '16:51'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:51'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '151' cm	Jacob sekinger (b) (4)	06 Nov 2020 14:42:04
DataPoint set to visible.	(b) (4) System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '42' kg	Jacob sekinger (b) (4)	06 Nov 2020 14:42:04
DataPoint set to visible.	(b) (4) System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '99.2' F	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '90'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '16'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '128'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '80'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:19

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:50
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:19

US3412126

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:26:14

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:57
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:43:28

US3412126

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:26:14

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:05:57
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:43:28

US3412126

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:24:05

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:31:23
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'arranged for a visit - vis on 12-aug-2020' (Site from DM).	Melissa Fuson (b) (4)	06 Oct 2020 18:53:14
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:45:34
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:14
Data point term sent to Coder	System	27 Aug 2020 22:26:47
User entered 'Upper Respiratory Infection'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '05 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:15:01
Query 'Data is required. Please provide.' answered with 'SUBJECT DOES NOT RECALL TIME' (Site from System).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:01:01
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:58:55
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
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	18 Sep 2020 18:58:55
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	18 Sep 2020 18:58:55
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:58:55
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	27 Aug 2020 22:26:36
User entered '18 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:15:03
Query 'Data is required. Please provide.' answered with 'SUBJECT DOES NOT RECALL TIME ' (Site from System).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:01:11
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:00:44
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 18:58:55
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:26:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:26:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:26:02
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:26:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 22:26:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:26:36
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:21:34
Query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' answered with 'UPDATED ALL RECORDS' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 18:12:28
User opened query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:49:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:17
Data point term sent to Coder	System	27 Aug 2020 22:28:53
User entered 'Rib Pain'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '23 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Aug 2020 22:29:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 22:29:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:29:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 22:28:18
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Aug 2020 22:28:18
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:29:12
User entered '23 Aug 2020 UN:UN' (non-conformant).	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 19:07:34
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.'	(b) (4), (b) (6)	27 Aug 2020 22:29:04
answered with 'Subject went to emergency room but PI does not consider serious adverse event' (Site from System).		
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	27 Aug 2020 22:28:18
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:29:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:29:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:28:18
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:45:44
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:26
User entered 'USA-US061-2020-mRNA-1273-P301000004'	System	28 Aug 2020 17:08:18
User entered 'New'	(b) (4), (b) (6)	28 Aug 2020 17:08:18

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User closed query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 01:37:12
Query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' answered with 'this will not be updated. Streptococcus pneumoniae pneumonia was not detected in culture.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 23:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:43
User opened query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:46:39
User closed query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:53:01
Query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' answered with 'Site has not received the final culture report yet. term will be updated if applicable. ' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:06:27
Query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' answered with 'Subject is refusing to proceed on with study at this point as she is waiting for a consult with a rheumatologist. ' (Site from DM).	Steven Anderson (b) (4)	21 Oct 2020 19:06:07
User opened query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:59
User opened query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:50:06

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:25
Data point term sent to Coder	System	27 Aug 2020 22:31:58
User entered 'Pneumonia'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:07
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:09
User entered '23 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:10
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:49:57
Query 'PV query: Please clarify when is the start date. November 23 is the hospitalization date.' answered with 'this is correct per medical records. Subject went to ER due to sharp pain from coughing. Subject was admitted that night and diagnosed with pneumonia.' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 19:58:52
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	24 Nov 2020 19:55:06
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	24 Nov 2020 19:55:06
User opened query 'PV query: Please clarify when is the start date. November 23 is the hospitalization date.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:05:46
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 18:50:06
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
User entered '14 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:55
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 06:07:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'recovering resolving, updated.' (Site from System).	Jacob sekinger (b) (4)	27 Oct 2020 18:17:08
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	26 Oct 2020 18:21:26
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:35
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the end date, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:34:03
User entered empty.	System	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:33
User closed query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety). Query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' answered with 'AS PER PROTOCOL AND HOSP IS CONSIDERED GRADE 4' (Site from Safety).	(b) (4), (b) (6) Mylene Asmar-Rios (b) (4)	20 Sep 2020 20:21:11 18 Sep 2020 19:02:17
Query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:45:50
User opened query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:32:43
User opened query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:16:55
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:34:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 22:34:34
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:34:34
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:30:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:26
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
Query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:04:15
User opened query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:03:40
	(b) (4), (b) (6)	04 Nov 2020 17:33:25
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		18 Sep 2020 19:08:28
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 19:08:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	27 Aug 2020 22:30:57
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:17
User entered '23 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:21
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:25
Query 'PV query: Please provide the discharge date, when available.' answered with '01 SEP 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:42
User entered '01 Sep 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:28
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:35:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:08
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:10:34
User closed query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:23:46
Query 'PV Query: Did the subject require admission to the intensive care unit?' answered with 'NO' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:12:31
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Sep 2020 19:08:28
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	18 Sep 2020 19:08:28
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:28
User opened query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:33:27
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	27 Aug 2020 22:30:57
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:32:59
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		21 Sep 2020 14:10:34
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		21 Sep 2020 14:10:34
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:23:46
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:02
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:03
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:05
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

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)	25 Nov 2020 03:43:45
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:17
User closed query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:50:22
User entered 'None (NONE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 19:59:23
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 'This was updated to other because it was the patients decision to discontinue IP.' (Site from System).	Steven Anderson (b) (4)	24 Nov 2020 19:50:49
Query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' answered with 'this has been filled out' (Site from CRA).	Steven Anderson (b) (4)	24 Nov 2020 19:49:08
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	18 Nov 2020 14:11:53
User closed query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:49
User opened query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:38
User closed query 'Please complete Dose Discontinuation CRF in End of Study folder' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:38
Query 'Please complete Dose Discontinuation CRF in End of Study folder' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:15:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:15:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' answered with 'This was due to SAE. subject has not stated that she wants to continue in the study. HOwever, she did miss visit 2 dosing due to SAE.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:13:14
User opened query 'Please complete Dose Discontinuation CRF in End of Study folder' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:27:04
User opened query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:25:46
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:58:15
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 18:51:31
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	20 Nov 2020 18:51:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 04:58:17
User closed query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 04:58:12
Query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' answered with 'this list will be updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:17:08
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:16:55
	(b) (4)	
User opened query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:27:57
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:26:39
	(b) (4)	
User closed query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:42
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)	20 Sep 2020 20:21:39
Query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' answered with 'OK' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:14:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
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 'OK ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:13:58
Query 'Per ETRTR: Please ensure reporting on EDC CRF ConMeds page treatment during hospitalization and home treatment, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:16
User opened query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:38:06
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)	03 Sep 2020 13:32:03
User opened query 'Per ETRTR: Please ensure reporting on EDC CRF ConMeds page treatment during hospitalization and home treatment, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:23:11
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:58:45
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:26:39
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:27
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 'Subject has recovered as of 14nov2020' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 19:55:32
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	24 Nov 2020 19:55:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4)	24 Nov 2020 19:55:06
Data Entry Error	(b) (4)	
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)	20 Nov 2020 23:05:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:58:49
User closed query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 04:58:41
Query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' answered with 'CRC's note is unclear and subject is still having problems requiring doctors visits and CT scans. site is trying to follow up with patient but she will not allow medical records to be obtained.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:23:47
User opened query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:21:38
Query 'PV Query: Query response states that outcome is resolved; however, outcome field not updated in EDC. If outcome is resolved, please update field in EDC. If not resolved, please leave this query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 17:15:36

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 18:18:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:21:26
User opened query 'PV Query: Query response states that outcome is resolved; however, outcome field not updated in EDC. If outcome is resolved, please update field in EDC. If not resolved, please leave this query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:04
User closed query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:55:22
Query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' answered with 'resolved' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:11:15
User opened query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:34:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:58:54
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:04:38
Query 'PV Query: Did the subject require admission to the intensive care unit?' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:04:22
User opened query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:03:49
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)	20 Nov 2020 23:03:09
User closed query 'please clarify narrative - (b) (6) (b) (6) also subject had bronchoscopy not endoscopy. add status update after post-discharge antibiotics' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:12
User closed query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 01:37:27
User closed query 'PV Query: (b) (6) (b) (6) (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 01:37:22
User closed query 'please rewrite narrative to provide complete picture of events - include culture results, etc, ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 04:59:08
Query 'please rewrite narrative to provide complete picture of events - include culture results, etc, ' answered with 'updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:43
Query 'please clarify narrative - (b) (6) (b) (6) ; also subject had bronchoscopy not endoscopy. add status update after post-discharge antibiotics' answered with 'updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:39

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'CALLED AND SPOKE TO SUBJECT. SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA AND ADMITTED TO ST ELIZABETH HOSPITAL FOR IV ANTIBIOTICS. bronchoscopy WAS DONE ON 25AUG2020 AND WAITING FOR CULTURE RESULTS PER SUBJECT. SHE SAID THEY WILL DISCHARGE HER ONCE THEY GET THE CULTURE RESULTS, THEY CAN PUT HER ON THE CORRECT ANTIBIOTICS FOR HOME. SUBJECT STATED FEELING MUCH BETTER AND COUGH IS MUCH IMPROVED. UPDATE: (b) (6) FEMALE WITH CHEST PAIN. PT HAS SEVERE, SHARP PAIN, WORSE WITH COUGHING. PAIN LOCATED ON RIGHT SIDE. PT WAS GIVEN COVID 19 VACCINE ON 8/4/20 AND HAD PAIN STARTING THE FOLLOWING DAY. FELT LIKE SHE HAD A BROKEN RIB. SHE IS A SMOKER. ASSOCIATED SYMPTOMS INCLUDE POOR APPETITE, DYSPNEA. PATIENT WAS FOUND TO HAVE CAVITARY PNA. NOW S/P BRONCH. ID ON BOARD FOR ABX MANAGMENT. PLAN FOR LONG TERM IV ABX AT HOME (ZOSYN) FOR AN ADDITIONAL 3 WEEKS. CRX WITH STABLE EXTENSIVE R MIDDLE LOVE INFILTRATE/ CONSOLIDATION WITH KNOWN INTRAPARENCHYMAL ABSCESS. Initial labs showed leucocytosis, blood cx so far ngtd. ct showed multifocal consolidation and fluid in the RML concerning for abscess. seen by pulmonology, underwent bronchoscopy with BAL on 8/25/20. BAL cultures and cytology pending ID was consulted for antibiotic management. Culture results Staphylococcus aureus was not detected strep pneumo antigen was not	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:34

Narrative

FDA-CBER-2022-1614-5912121

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'PER EDC QUERY SITE IS FAXING MEDICAL RECORDS OBTAINED FOR SUBJECT US3412126 TO DATA SAFETY TEAM PER STEVEN ANDERSON 21-OCT-20' (Site from Safety).	Melissa Fuson (b) (4)	30 Oct 2020 18:00:07
User closed query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).'	(b) (4), (b) (6)	22 Oct 2020 16:53:11
Query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).'	Steven Anderson (b) (4)	21 Oct 2020 19:19:59
Query 'Please update narrative per hospital records ' answered with 'narrative has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Oct 2020 19:19:25

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CALLED AND SPOKE TO SUBJECT. SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA AND ADMITTED TO ST ELIZABETH HOSPITAL FOR IV ANTIBIOTICS. ENDOSCOPY WAS DONE ON 25AUG2020 AND WAITING FOR CULTURE RESULTS PER SUBJECT. SHE SAID THEY WILL DISCHARGE HER ONCE THEY GET THE CULTURE RESULTS, THEY CAN PUT HER ON THE CORRECT ANTIBIOTICS FOR HOME. SUBJECT STATED FEELING MUCH BETTER AND COUGH IS MUCH IMPROVED. Update: (b) (6) female with chest pain. Pt has severe, sharp pain, worse with coughing. Pain located on right side. Pt was given COVID 19 vaccine on 8/4/20 and had pain starting the following day. Felt like she had a broken rib. She is a smoker. associated symptoms include poor appetite, dyspnea. Patient was found to have cavitory PNA. Now s/p bronch. ID on board for abx managment. plan for long term IV abx at home (zosyn) for an additional 3 weeks. CRX with stable extensive R middle love infiltrate/ consolidation with known intraparenchymal abscess.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:19:12
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:55:37
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:10:32

v6.020 DTW (1102)

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US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:37
User opened query 'Please update narrative per hospital records ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:19:09
User closed query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:55:25
User closed query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:55:24
Query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' answered with 'no thromboembolic diagnosis' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:17:35
Query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' answered with 'strep pneumo' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:17:14
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'ok' (Site from DM).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:11:36
User opened query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 19:06:06
User opened query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 19:05:53
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:27:41
User closed query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:16

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:13
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:11
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pt. has finds bilaterally pneumonia. Questionable abscess. Elevated WBC 21.8, D dimer 1,911. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:22:36
Query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' answered with 'As per Hospital records patient was COVID-19 negative on 22 AUG 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:16:06
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'As per Hospital Records 22 AUG 2020 patient tested negative for COVID-19' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:15:30
Query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' answered with 'Oxygen levels were 98% no supplement oxygen was needed. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:07:39
User closed query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:50

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' answered with 'ENDOBRONCHIAL FINDINGS : NO MASSES. THE FOLLOWING: TRACHEA, CARINA, RIGHT MAIN BRONCHUS, RIGHT UPPER LOBE BRONCHUS, RIGHT MIDDLE LOBE BRONCHIUS, RIGHT LOWER LOBE BRONCHUS ALL SHOW NORMAL MUCOSA. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:23:28
Query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:21
Query 'Per ETRTR: Please confirm within Narrative the date of site call contact with subject (date of site awareness), thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:20
Query 'Per ETRTR: Please confirm whether subject was tested for COVID-19 and provide results, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:19
User opened query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:39:18
User opened query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:38:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:37:37
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:37:07
User opened query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:36:05
User opened query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:21:54

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please confirm within Narrative the date of site call contact with subject (date of site awareness), thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:21:19
User opened query 'Per ETRTR: Please confirm whether subject was tested for COVID-19 and provide results, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:19:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Aug 2020 22:34:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 22:34:34
User entered 'Called and spoke to subject. She stated she went to the emergency room on 23Aug2020 for rib pain from coughing. She thought she broke a rib and wanted to get it wrapped. She stated that they did a chest x-ray and was diagnosed with pneumonia and admitted to St Elizabeth hospital for IV antibiotics. Endoscopy was done on 25Aug2020 and waiting for culture results per subject. She said they will discharge her once they get the culture results, they can put her on the correct antibiotics for home. Subject stated feeling much better and cough is much improved. Will request discharge summary,' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:34:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Aug 2020 22:30:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:10:34
User entered '1'	System	18 Sep 2020 19:23:46
User entered '0'	System	27 Aug 2020 22:30:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:58:26
User opened query 'Subject received Rocephrin (p. 13), Azithromycin (p. 13), Zofran (pp. 24- 25) and morphine (p. 24-25) per hospital records? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:36:02
User opened query 'hospital records mention Solumedrol and lovenox -please confirm not given or add to Con Meds if appropriate' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:33:03
Query 'please check hospital records and confirm not given or add to Con Meds' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:32:04
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:31:55
User opened query 'please check hospital records and confirm not given or add to Con Meds' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:31:36
User closed query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:31:36
Query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' answered with 'please see entry line 15 in con meds.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	27 Oct 2020 18:36:41
User closed query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, and #8 edary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:20:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:20:00
Query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, Jacob sekinger and #8 edairy reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4)	20 Oct 2020 15:29:04
Query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' answered with 'solumedrol and lovenox were not reported on source documents. ' (Site from CRA).	Jacob sekinger (b) (4)	20 Oct 2020 15:21:42
User opened query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, and #8 edairy reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 05:00:23
User opened query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:17:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:30:44
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:39:54

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:23:43
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 Sep 2020 15:23:43
Data point term sent to Coder	System	21 Sep 2020 14:39:28
User entered 'oxycodone-acetaminophen'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/325' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:11:36
User entered '7.5/325'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[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: CARTIA [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:45
Data point term sent to Coder	System	21 Sep 2020 14:40:31
User entered 'cartia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:16:46
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:16:46
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:46
Data point term sent to Coder	System	21 Sep 2020 14:40:32
User entered 'celexa'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:20:30
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'REVIEWED AND UPDATED START DATE TO 2015' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 18:14:57
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:27:55
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:41
Data point term sent to Coder	System	21 Sep 2020 14:42:33
User entered 'diclofenac'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '75'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:45:35
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 Sep 2020 14:45:35
Data point term sent to Coder	System	21 Sep 2020 14:43:37
User entered 'furosemide'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:57:43
Data point term sent to Coder	System	21 Sep 2020 14:57:10
User entered 'potassium chloride'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:19:18
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:14:44
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 Sep 2020 15:14:44
Data point term sent to Coder	System	21 Sep 2020 14:58:12
User entered 'tizanidine hydrochloride'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'osteoarthritis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:32:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'UPDATED START DATE PER MEDICAL HISTORY TO 2010' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 18:15:52
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:29:58
User entered 'un UNK 2010'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 10:08:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 10:08:16
Data point term sent to Coder	System	20 Nov 2020 19:20:51
Coding entries removed.	Melissa Fuson (b) (4)	20 Nov 2020 19:20:12
User entered 'CALCIUM CHLORIDE - 10%' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:20:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:31:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:31:34
Data point term sent to Coder	System	26 Oct 2020 17:19:18
Coding entries removed.	Melissa Fuson (b) (4)	26 Oct 2020 17:18:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 00:47:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 00:47:56
Data point term sent to Coder	System	21 Sep 2020 14:59:14
User entered 'calcium chloride'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:31:01
User entered 'OSTEOPOROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:18:46
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'VERIFIED SOURCE AND ADDED OSTEOPOROSIS TO MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 17:18:26
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:27:19
User entered 'osteoporosis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:48:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:48:14
Data point term sent to Coder Coding entries removed.	System Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:19:19 26 Oct 2020 17:19:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:02:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:02:41
Data point term sent to Coder User entered 'prolia'	System Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:20 21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:05:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:04:52
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:18:36
User entered 'OSTEOPOROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:19:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'OSTEOPOROSIS WAS CROSSED OFF MEDICAL HISTORY ON 04-SUG-2020 VIA SOURCE' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 17:10:45
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:29:23
User entered 'osteoporosis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	01 Oct 2020 14:20:51
User entered 'other (OTHER)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:20:51
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	21 Sep 2020 15:01:23
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'two times per year'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:22:52
User entered 'UN UNK 2015' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:17:44
User entered 'un UNK 2018'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:17:44
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:09:53
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:17:44
User entered '04 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:09:53
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '1'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '1'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '804 (804)'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:21:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:21:39
Data point term sent to Coder	System	21 Sep 2020 15:02:20
User entered 'aspirin'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:05
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:06
User entered 'uri'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:08
User entered '81'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:10
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:14
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:16
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:17
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:19
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:21
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:25
User entered '05 Aug 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:27
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:29
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:19:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'RECORDED STOP DATE OF 18 AUG 2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:24:05
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:23:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:26:50
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:31
User entered '18 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:23:48
User entered empty.	(b) (4)	
	Mylene Asmar-Rios	21 Sep 2020 15:02:17
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:46
Data point term sent to Coder	System	20 Nov 2020 19:25:54
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:25:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:06:45
Data point term sent to Coder	System	21 Sep 2020 15:05:32
User entered 'guaifenesin'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'SAR' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:25:36
User entered 'pneumonia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:25:36
User entered '01 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:22:45
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 Sep 2020 15:22:45
Data point term sent to Coder	System	21 Sep 2020 15:08:38
User entered 'piperacillin-tazobactam'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:09
User entered 'pneumonia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:11
User entered '3.375'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:13
User entered 'g (g)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:34
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:36
User entered 'other (OTHER)'	Mylene Asmar-Rios	21 Sep 2020 15:08:15
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

If frequency is Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'UPDATED TO THREE TIMES DAILY - SOURCE HAS Q EVERY 8 HOURS' (Site from DM).	Melissa Fuson (b) (4)	20 Nov 2020 19:15:13
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:04:07
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:04:00
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:02:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:38
User entered 'every 8 hours'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:40
User entered 'Intravenous (INTRAVENOUS)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:42
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:47
User entered '01 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:51:22
User closed query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:51:20
Query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:57:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 23:57:36
User opened query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:37:23
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:51:23
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 23:57:36
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 23:57:36
DataPoint Verified.	Steven Anderson (b) (4)	10 Nov 2020 23:57:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:30
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:08:15
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:28
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:07:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:07:48
Data point term sent to Coder	System	20 Nov 2020 19:31:00
Query 'Please correct 3/325 to 5/325' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:57:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:57:47
Data point term sent to Coder	System	10 Nov 2020 23:59:10
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 23:58:57
Coding entries removed.	(b) (4) Steven Anderson (b) (4)	10 Nov 2020 23:58:57
User entered 'OXYCODONE- ACEAMINOPHEN (5/325MG TABLET)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:58:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:03
User opened query 'Please correct 3/325 to 5/325' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:40:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 05:08:43

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 05:08:43
Data point term sent to Coder	System	26 Oct 2020 18:19:15
User entered 'OXYCODONE- ACEAMINOPHEN (3/325MG TABLET)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:18:32
Data point term sent to Coder	System	26 Oct 2020 18:18:14
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:18:01
User entered 'OXYCODONE- ACEAMINOPHEN (3-325MG TABLET)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:18:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:24:42
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 Sep 2020 15:24:42
Data point term sent to Coder	System	21 Sep 2020 15:09:44
User entered 'oxycodone- aceaminophen'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:05
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
Query 'should this be pain related to pneumonia?' answered with 'NO IS RELATED TO OA PER SOURCE DOCUMENT CHANGED ON 19-NOV-2020' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:31:35
User entered 'OA' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:30:58
User opened query 'should this be pain related to pneumonia?' (Site from CRA).	(b) (4), (b) (6) (b) (4)	04 Nov 2020 17:41:14
User entered 'pneumonia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:41:19
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:35:28
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'UPDATED TO THE 3/25MG DOSAGE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:18:26
User entered '5/325' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:18:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:28:43
User entered '1'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:41:20
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:18:01
User entered 'tablet (TABLET)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:41:25
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:41:28
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 19:30:58
	(b) (4)	
User entered 'UN UNK 2019' reason for change:	Melissa Fuson (b) (4)	20 Nov 2020 19:30:58
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:41:30
User entered '01 Sep 2020'	Mylene Asmar-Rios	21 Sep 2020 15:09:34
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:16
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'please confirm ongoing as symptoms resolved 22 Sep 2020' answered with 'PER SOURCE THIS IS ONGOING WHICH WAS CHANGED ON 19NOV-2020' (Site from CRA). DataPoint Verified.	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:32:22
	(b) (4), (b) (6)	04 Nov 2020 17:42:12
User opened query 'please confirm ongoing as symptoms resolved 22 Sep 2020' (Site from CRA). User entered 'Yes (Y)'	(b) (4), (b) (6) Mylene Asmar-Rios (b) (4)	04 Nov 2020 17:42:07 21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:25
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 15:09:34

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:30:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:30:16
Data point term sent to Coder	System	20 Nov 2020 19:38:35
Data point term sent to Coder	System	20 Nov 2020 19:35:30
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:35:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:55:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 22:55:24
Data point term sent to Coder	System	06 Oct 2020 19:24:21
Data point term sent to Coder	System	06 Oct 2020 19:22:04
User entered 'BENZONATATE'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:56
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from DM).	Melissa Fuson (b) (4)	20 Nov 2020 19:37:59
User entered 'URI - UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 19:37:39
Query 'please consider updating to URI as indicated in source' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from CRA).	Melissa Fuson (b) (4)	20 Nov 2020 19:36:18
User entered 'URI' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:35:18
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:04:24
User opened query 'please consider updating to URI as indicated in source' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:44:04
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:08
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:58
User entered 'ONGOING MILD INTERMITTENT COUGH' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:22
User entered 'URNIARY TRACT INFECTION FOR AE EVENT'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:00
User entered '200'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:02
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:13
User entered 'three times daily (TID)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:20
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:24
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:28
User entered '14 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:22
User entered '05 Aug 2020'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:29
User entered '0'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:32:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:31
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:33
User entered '18 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:32:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 19:23:31
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Oct 2020 19:23:22
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	06 Oct 2020 19:22:06
User entered '18 Aug 2020' reason for change: Data Entry Error	System	06 Oct 2020 19:22:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41
User entered '18 Aug ' (non-conformant).	(b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from DM).	Melissa Fuson (b) (4)	20 Nov 2020 19:38:40
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:04:35
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:29:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 15:29:38
Data point term sent to Coder	System	20 Oct 2020 15:28:51
User entered 'aspirin'	Jacob sekinger (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'fever'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:27:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:27:34
Data point term sent to Coder	System	26 Oct 2020 17:28:43
User entered 'NASACORT - 55MCG'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'SEASONAL ALLERGIES'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '55'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '08 Oct 2019' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:30:54
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	26 Oct 2020 17:28:23
User entered '08 Oct 1999' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	26 Oct 2020 17:27:42
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 17:28:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 17:28:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 17:27:42
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
User entered '8 Oct 2019'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: MOMETASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:31:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:31:34
Data point term sent to Coder	System	26 Oct 2020 17:30:45
User entered 'MOMETASONE - 50MCG'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'SEASONAL ALLERGIES'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '20 Aug 2019'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
Data point term sent to Coder	System	19 Nov 2020 20:42:59
User entered 'morphine'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '8'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:26:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Query 'please add daily ECGs start 23 Aug 2020 - 30 Aug 2020' answered with 'ADDED ALL PROCEDURES ' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 14:58:37
Query 'please add chest xray on 31 Aug 2020 and PICC line insertion on 31 Aug 2020' answered with 'ADDED ALL PROCEDURES ' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 14:58:33
Query 'please add CT pulmonary angiogram on 22 Aug 2020, Chest xray 22 Aug 2020 any cultures done?' answered with 'ADDED ALL PROCEDURES AND CULTURES WERE NOT DONE.' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 14:58:26
User opened query 'please add daily ECGs start 23 Aug 2020 - 30 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:37:10
User opened query 'please add chest xray on 31 Aug 2020 and PICC line insertion on 31 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:30:15
User opened query 'please add CT pulmonary angiogram on 22 Aug 2020, Chest xray 22 Aug 2020 any cultures done?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:12:26
User closed query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:12:26
Query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	22 Oct 2020 18:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	22 Oct 2020 18:06:32
User opened query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:14:50
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:39:58

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:52:24
User entered '25 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 19:07:25
	(b) (4)	
User entered 'PNEUMONIA (WITH A BRONCHOSCOPY WITH BAL DONE ON 25-AUG-2020)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:07:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:52:26
User entered 'bronchoscopy with BAL'	Jacob sekinger (b) (4)	22 Oct 2020 18:07:36
	(b) (4)	

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
Query 'please consider updating to pneumonia since this was done as part of SAE diagnostics' answered with 'UPDATED PROCEDURE / SURGERY ' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:07:40
User opened query 'please consider updating to pneumonia since this was done as part of SAE diagnostics' (Site from CRA).	(b) (4), (b) (6) (b) (4)	04 Nov 2020 16:54:40
User entered 'Medical History (MH)'	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:52:29
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'X-RAY CHEST (PA&LATERAL)'	Melissa Fuson (b) (4)	23 Nov 2020 14:49:26
reason for change: Data Entry Error	(b) (4)	
User entered 'X-RAY CHEST'	Melissa Fuson (b) (4)	23 Nov 2020 14:45:45
	(b) (4)	

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:00

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'X-RAY RIBS'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:00

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:00

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:00

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CT PULMONARY ANGIOGRAM'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SECOND XRAY CHEST (PA&LATERAL)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'PICC LINE INSERTION'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:26:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'ECG's DAILY FROM 23-AUG-2020 TO 30-AUG-2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:26:14

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:26:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:14

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:14

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:14

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

Audit	User	Time (GMT)
User entered 'Patients decision to not come in for second injection and also not following any protocol requirements'	Steven Anderson (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '28/Aug/2020 13:09'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '20/Sep/2020 16:22'	System	20 Sep 2020 20:22:29

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:11:30
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 20:22:29

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '22/Sep/2020 09:11'	System	22 Sep 2020 13:11:42

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:55:35
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 13:11:42

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '02/Oct/2020 08:55'	System	02 Oct 2020 12:55:43

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:55:43

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '22/Oct/2020 16:53'	System	22 Oct 2020 16:53:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:54:17
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 16:53:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6) '	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '27/Oct/2020 13:19'	System	27 Oct 2020 13:19:33

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:06:15
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 13:19:33

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '28/Oct/2020 09:06'	System	28 Oct 2020 13:06:23

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:28:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 13:06:23

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '12/Nov/2020 01:29'	System	12 Nov 2020 01:29:34

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:32:55
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 01:29:34

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE-USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:26:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '23/Nov/2020 21:33'	System	23 Nov 2020 21:33:05

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:26:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 21:33:05