

US3412127 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:26:55

All time stamps listed in this document are displayed in GMT

US3412127

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:55

[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 09:26:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 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 09:26:55

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	05 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 09:26:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

Condition	PTSD
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

Condition	LUMBAR PAIN
Start date (dd MMM yyyy)	UN JAN 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:56 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 07:56
Height (<i>xxx.x</i>)	170 cm
Weight (<i>xxx.x</i>)	72.5 kg
BMI (<i>xxx.x</i>)	25.08651 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 09:26:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒
	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 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 09:26:55

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101177

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 09:26:55

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 09:26:55

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)	5 AUG 2020
Time of assessment (00:00-23:59)	07:56 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 07:56
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 09:26:55

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)	5 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 09:25
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

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 09:26:55

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)	05 AUG 2020
What was the treatment time? (00:00-23:59)	08:55 (24 HR)
Treatment Date and Time (derived)	05 AUG 2020 08:55
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 09:26:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	5 AUG 2020
Collection time (<i>00:00-23:59</i>)	08:22 (24 HR)
Collection date and time (derived)	5 AUG 2020 08:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:55

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:24	5 AUG 2020 08:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

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 09:26:55

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

05 AUG 2020 09:31

PC Open Date & Time

05 AUG 2020 09:15

PC Close Date & Time

05 AUG 2020 11:45

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	05 AUG 2020 18:12
PC Open Date & Time	05 AUG 2020 12:40
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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 06 AUG 2020 18:03

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(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:05

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 11:19

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 17:48

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

11 AUG 2020 18:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

05 AUG 2020 09:32

PC Open Date & Time

05 AUG 2020 09:15

PC Close Date & Time

05 AUG 2020 11:45

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 18:12

PC Open Date & Time

05 AUG 2020 12:40

PC Close Date & Time

06 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

06 AUG 2020 18:04

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

07 AUG 2020 18:03

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

08 AUG 2020 18:05

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

10 AUG 2020 11:19

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

10 AUG 2020 17:48

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

11 AUG 2020 18:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 09:32
PC Open Date & Time	05 AUG 2020 09:15
PC Close Date & Time	05 AUG 2020 11:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 18:13
PC Open Date & Time	05 AUG 2020 12:40
PC Close Date & Time	06 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	06 AUG 2020 18:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	07 AUG 2020 18:03
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	08 AUG 2020 18:06
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	10 AUG 2020 17:48
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	11 AUG 2020 18:02
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	17:25 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 17:25
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	18:48 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 18:48
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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)	03 SEP 2020
What was the treatment time? (00:00-23:59)	18:17 (24 HR)
Treatment Date and Time (derived)	03 SEP 2020 18:17
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

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	03 SEP 2020
Collection time (<i>00:00-23:59</i>)	17:40 (24 HR)
Collection date and time (derived)	03 SEP 2020 17:40

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:55

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:43	03 SEP 2020 17:43
Nasopharyngeal Swab 2	No		

US3412127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 18:51

PC Open Date & Time

03 SEP 2020 18:37

PC Close Date & Time

03 SEP 2020 21:07

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

04 SEP 2020 06:03

PC Open Date & Time

03 SEP 2020 22:02

PC Close Date & Time

04 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

04 SEP 2020 15:43

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

05 SEP 2020 12:09

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 13:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

07 SEP 2020 15:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 05:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

03 SEP 2020 18:52

PC Open Date & Time

03 SEP 2020 18:37

PC Close Date & Time

03 SEP 2020 21:07

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 06:05

PC Open Date & Time

03 SEP 2020 22:02

PC Close Date & Time

04 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

4

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

04 SEP 2020 15:42

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

05 SEP 2020 12:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

06 SEP 2020 13:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

07 SEP 2020 15:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 SEP 2020 05:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:52
PC Open Date & Time	03 SEP 2020 18:37
PC Close Date & Time	03 SEP 2020 21:07

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 06:06
PC Open Date & Time	03 SEP 2020 22:02
PC Close Date & Time	04 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	04 SEP 2020 15:42
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	05 SEP 2020 12:10
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	06 SEP 2020 13:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	07 SEP 2020 15:33
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	09 SEP 2020 05:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

Yes ☐	
PC Time stamp	09 SEP 2020 17:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

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.

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:31 (24 HR)
Collection date and time (derived)	02 OCT 2020 12:31

US3412127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 OCT 2020 18:46:51
Patient Cloud Open Date & Time	05 OCT 2020 00:01
Patient Cloud Close Date & Time	09 OCT 2020 23:59

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 18:03:27
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 06:22:43
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 09:25:40
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 18:30:43
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

06 OCT 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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°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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 06:15:05
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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°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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 FEB 2021 00:01

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16 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 FEB 2021 00:01

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02 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 MAR 2021 00:01

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09 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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°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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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°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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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15 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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10 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 MAY 2022 00:01

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31 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 JUN 2022 00:01

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14 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 JUN 2022 00:01

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28 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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05 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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12 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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02 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

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

US3412127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412127

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
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 ☐

US3412127

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:26:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

AEID	USA-US061-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE RESPIRATORY FAILURE
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)	14 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)	20 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	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	20 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

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US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

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	True
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	

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

SUBJECT US3412127 WAS
ADMITTED FOR ACUTE
REPIRATORY FAILURE AND
SUSPECTED RESPIRATORY
INFECTION. INFECTIOUS
DISEASE CONSULTED. HE WAS
TREATED WITH LEVAQUIN
AND SOLUMEDROL. HE
IMPROVED ACCORDINGLY.
PATIENT WAS TESTED FOR
COVID-19 AND REMAINED
NEGATIVE.

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

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:55

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

Yes ☒

No ☐

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

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

	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 2012
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	☒

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	TRINTELLIX
Prophylaxis	Yes ☐ No ☒
Indication	PTSD
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

	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 2012
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	☒

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	WELLBUTRIN
Prophylaxis	Yes ☐ No ☒
Indication	PTSD
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

	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 2012
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	☒

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	SOLICITED PAIN - MYALGIA AND JOINT ACHES
Dose per administration	800
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

	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)		06 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		06 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
Dose per administration	90
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

	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)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes ☐ No ☒
Indication	UPPER RESPIRATORY INFECTION
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

	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)		16 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		24 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

	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)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		24 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	SOLUMEDROL
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
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	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

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)	17 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	19 AUG 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	ONDANSTERON
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

	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)		17 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	SODIUM CHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
Dose per administration	0.9
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PERCENT
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

	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)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	SYMBICORT
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
Dose per administration	160/4.5
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

	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)	26 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE RESPIRATORY FAILURE
Dose per administration	90
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

	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 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	☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	LUMBAR PAIN
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 ☐

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

	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 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3412127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:55

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412127

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3412127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:26:55

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 ☐

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	18/AUG/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

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:19
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

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 22:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:55

SAEID	USA-US061-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	15/OCT/2020 07:47
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

US3412127 (Prod: New Horizons Clinical Research)

US3412127

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:55

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3412127'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Aug 2020 11:49:19

US3412127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 11:49:20

US3412127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 11:49:21

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Age](#)

Audit	User	Time (GMT)
User entered '42'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '42'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

White

Audit	User	Time (GMT)
User closed query 'Race has not been provided. Please correct.' (Site from System).	System	05 Aug 2020 12:40:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 12:40:21
User opened query 'Race has not been provided. Please correct.' (Site from System).	System	05 Aug 2020 12:40:06
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:55

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '05 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 11:49:20

US3412127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:19:14

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:21:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:21:18
Data point term sent to Coder	System	14 Aug 2020 17:20:12
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	18 Aug 2020 21:40:31
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Aug 2020 17:19:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:40:31
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

[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)	14 Aug 2020 17:21:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:21:18
Data point term sent to Coder	System	14 Aug 2020 17:20:13
User entered 'ANXIETY'	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:22:28
Data point term sent to Coder	System	14 Aug 2020 17:21:14
User entered 'DEPRESSION'	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:22:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:22:29
Data point term sent to Coder	System	14 Aug 2020 17:21:14
User entered 'PTSD'	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

[Condition](#)

Audit	User	Time (GMT)
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: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:51:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:51:24
Data point term sent to Coder	System	22 Oct 2020 21:50:39
User entered 'lumbar pain'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'un Jan 2018'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '2018'	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '07:56'	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 07:56'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '170' cm	(b) (4), (b) (6)	14 Aug 2020 17:25:13
DataPoint set to visible.	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '72.5' kg	(b) (4), (b) (6)	14 Aug 2020 17:25:13
DataPoint set to visible.	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '25.08651'	System	16 Sep 2020 23:43:29
User entered '25.1'	System	14 Aug 2020 17:25:13
DataPoint set to visible.	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 17:25:13
DataPoint set to visible.	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:39:38
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:25:26
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 17:25:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:25:44

US3412127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 22:20:09
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:25:44

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '05 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

[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 02:09:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:09:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 12:34:10
User entered '101177' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

[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) 	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

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)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:55

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '07:56'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 07:56'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:55

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User closed 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).	(b) (4), (b) (6)	18 Aug 2020 11:07:59
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:29:36
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).		14 Aug 2020 17:29:27
User entered '09:25'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 09:25'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:29:42

US3412127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:29:42

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '05 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '08:55'	(b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 08:55'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:22'	(b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 08:22'	System	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:24'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '5 Aug 2020 08:24'	System	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:31:16

US3412127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:31:16

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:30:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e2537d27-4fd8-4e0f-bfb1-4ce063e920ef'	System	05 Aug 2020 13:31:11
User entered 'Yes (Y)'	System	05 Aug 2020 13:31:11

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:30:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e2537d27-4fd8-4e0f-bfb1-4ce063e920ef'	System	05 Aug 2020 13:31:11
User entered '98.1'	System	05 Aug 2020 13:31:11

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:31:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e2537d27-4fd8-4e0f-bfb1-4ce063e920ef'	System	05 Aug 2020 13:31:11
User entered 'No (N)'	System	05 Aug 2020 13:31:11

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:31:09', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e2537d27-4fd8-4e0f-bfb1-4ce063e920ef'	System	05 Aug 2020 13:31:11
User entered '05 Aug 2020 09:31'	System	05 Aug 2020 13:31:11

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:15'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:45'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:47', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b34be25a-9c9d-479f-a845-73ee0bf04565'	System	05 Aug 2020 22:13:03
User entered 'Yes (Y)'	System	05 Aug 2020 22:13:03

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b34be25a-9c9d-479f-a845-73ee0bf04565'	System	05 Aug 2020 22:13:03
User entered '98.6'	System	05 Aug 2020 22:13:03

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b34be25a-9c9d-479f-a845-73ee0bf04565'	System	05 Aug 2020 22:13:03
User entered 'No (N)'	System	05 Aug 2020 22:13:03

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b34be25a-9c9d-479f-a845-73ee0bf04565'	System	05 Aug 2020 22:13:03
User entered '05 Aug 2020 18:12'	System	05 Aug 2020 22:13:03

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:40'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 2'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:02:50', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered 'Yes (Y)'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:02:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered '97.4'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered 'Yes (Y)'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User closed query 'Per CDM, subject reported medication to treat pain or fever however Prior/Concomitant Medication page is not completed. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 18:36:47
Query 'Per CDM, subject reported medication to treat pain or fever however Prior/Concomitant Medication page is not completed. Please complete page or provide explanation. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:55:59
User opened query 'Per CDM, subject reported medication to treat pain or fever however Prior/Concomitant Medication page is not completed. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 17:42:54
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).	(b) (4), (b) (6)	13 Aug 2020 17:42:40
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 'contacted subject' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 20:11:55
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).	System	06 Aug 2020 22:03:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:12', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered '1'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:12', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered '0'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e04ad9ae-03b0-44a3-b181-1688ea457de6'	System	06 Aug 2020 22:03:18
User entered '06 Aug 2020 18:03'	System	06 Aug 2020 22:03:18

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 3'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:02:44', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '14a08bce-ec11-4291-b594-f644acd61d4f'	System	07 Aug 2020 22:02:57
User entered 'Yes (Y)'	System	07 Aug 2020 22:02:57

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:02:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '14a08bce-ec11-4291-b594-f644acd61d4f'	System	07 Aug 2020 22:02:57
User entered '98.2'	System	07 Aug 2020 22:02:57

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:02:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '14a08bce-ec11-4291-b594-f644acd61d4f'	System	07 Aug 2020 22:02:57
User entered 'No (N)'	System	07 Aug 2020 22:02:57

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:02:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '14a08bce-ec11-4291-b594-f644acd61d4f'	System	07 Aug 2020 22:02:57
User entered '07 Aug 2020 18:02'	System	07 Aug 2020 22:02:57

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 4'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:04:44', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e9366212-42aa-4528-bfa2-413cf07ab1d6'	System	08 Aug 2020 22:05:27
User entered 'Yes (Y)'	System	08 Aug 2020 22:05:27

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e9366212-42aa-4528-bfa2-413cf07ab1d6'	System	08 Aug 2020 22:05:27
User entered '98.2'	System	08 Aug 2020 22:05:27

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e9366212-42aa-4528-bfa2-413cf07ab1d6'	System	08 Aug 2020 22:05:27
User entered 'No (N)'	System	08 Aug 2020 22:05:27

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:22', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e9366212-42aa-4528-bfa2-413cf07ab1d6'	System	08 Aug 2020 22:05:27
User entered '08 Aug 2020 18:05'	System	08 Aug 2020 22:05:27

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 5'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:18:56', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7f8736fa-a6db-450e-8005-83da3342c806'	System	10 Aug 2020 15:19:08
User entered 'Yes (Y)'	System	10 Aug 2020 15:19:08

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:01', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7f8736fa-a6db-450e-8005-83da3342c806'	System	10 Aug 2020 15:19:08
User entered '98.1'	System	10 Aug 2020 15:19:08

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:03', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7f8736fa-a6db-450e-8005-83da3342c806'	System	10 Aug 2020 15:19:08
User entered 'No (N)'	System	10 Aug 2020 15:19:08

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7f8736fa-a6db-450e-8005-83da3342c806'	System	10 Aug 2020 15:19:08
User entered '10 Aug 2020 11:19'	System	10 Aug 2020 15:19:08

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 6'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:47:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9f6f3b62-acfb-49fe-bb17-d60ea7ada016'	System	10 Aug 2020 21:48:14
User entered 'Yes (Y)'	System	10 Aug 2020 21:48:14

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9f6f3b62-acfb-49fe-bb17-d60ea7ada016'	System	10 Aug 2020 21:48:14
User entered '98.4'	System	10 Aug 2020 21:48:14

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9f6f3b62-acfb-49fe-bb17-d60ea7ada016'	System	10 Aug 2020 21:48:14
User entered 'No (N)'	System	10 Aug 2020 21:48:14

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:07', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9f6f3b62-acfb-49fe-bb17-d60ea7ada016'	System	10 Aug 2020 21:48:14
User entered '10 Aug 2020 17:48'	System	10 Aug 2020 21:48:14

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 7'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:01:54', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '50b562a3-3241-4b0b-8420-ec53f210707c'	System	11 Aug 2020 22:02:10
User entered 'Yes (Y)'	System	11 Aug 2020 22:02:10

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '50b562a3-3241-4b0b-8420-ec53f210707c'	System	11 Aug 2020 22:02:10
User entered '97.5'	System	11 Aug 2020 22:02:10

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '50b562a3-3241-4b0b-8420-ec53f210707c'	System	11 Aug 2020 22:02:10
User entered 'No (N)'	System	11 Aug 2020 22:02:10

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '50b562a3-3241-4b0b-8420-ec53f210707c'	System	11 Aug 2020 22:02:10
User entered '11 Aug 2020 18:02'	System	11 Aug 2020 22:02:10

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T09:31:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a086d62b-2475-4455-b38f-a2c8ba7d2be7'	System	05 Aug 2020 13:32:06
User entered 'None (1)'	System	05 Aug 2020 13:32:06

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:31:52', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a086d62b-2475-4455-b38f-a2c8ba7d2be7'	System	05 Aug 2020 13:32:06
User entered 'No (N)'	System	05 Aug 2020 13:32:06

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:31:56', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a086d62b-2475-4455-b38f-a2c8ba7d2be7'	System	05 Aug 2020 13:32:06
User entered 'No (N)'	System	05 Aug 2020 13:32:06

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T09:32:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a086d62b-2475-4455-b38f-a2c8ba7d2be7'	System	05 Aug 2020 13:32:06
User entered 'None (1)'	System	05 Aug 2020 13:32:06

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:03', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a086d62b-2475-4455-b38f-a2c8ba7d2be7'	System	05 Aug 2020 13:32:06
User entered '05 Aug 2020 09:32'	System	05 Aug 2020 13:32:06

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:15'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:45'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T18:11:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '29198890-dd18-48e5-a08c-9d0392a3a2c5'	System	05 Aug 2020 22:12:42
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 22:12:42

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '29198890-dd18-48e5-a08c-9d0392a3a2c5'	System	05 Aug 2020 22:12:42
User entered 'No (N)'	System	05 Aug 2020 22:12:42

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:16', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '29198890-dd18-48e5-a08c-9d0392a3a2c5'	System	05 Aug 2020 22:12:42
User entered 'No (N)'	System	05 Aug 2020 22:12:42

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T18:12:31', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '29198890-dd18-48e5-a08c-9d0392a3a2c5'	System	05 Aug 2020 22:12:42
User entered 'None (1)'	System	05 Aug 2020 22:12:42

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:12:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '29198890-dd18-48e5-a08c-9d0392a3a2c5'	System	05 Aug 2020 22:12:42
User entered '05 Aug 2020 18:12'	System	05 Aug 2020 22:12:42

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:40'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 2'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-06T18:03:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '83e5077f-c343-48f6-8228-9217198f0d89'	System	06 Aug 2020 22:04:11
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 22:04:11

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '83e5077f-c343-48f6-8228-9217198f0d89'	System	06 Aug 2020 22:04:11
User entered 'No (N)'	System	06 Aug 2020 22:04:11

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:03:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '83e5077f-c343-48f6-8228-9217198f0d89'	System	06 Aug 2020 22:04:11
User entered 'No (N)'	System	06 Aug 2020 22:04:11

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-06T18:04:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '83e5077f-c343-48f6-8228-9217198f0d89'	System	06 Aug 2020 22:04:11
User entered 'None (1)'	System	06 Aug 2020 22:04:11

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '83e5077f-c343-48f6-8228-9217198f0d89'	System	06 Aug 2020 22:04:11
User entered '06 Aug 2020 18:04'	System	06 Aug 2020 22:04:11

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 3'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[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 (c45938ec87da2c96)', Time: '2020-08-07T18:03:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f89581b4-29c4-4df0-b3b4-f3234e6fd884'	System	07 Aug 2020 22:03:20
User entered 'None (1)'	System	07 Aug 2020 22:03:20

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f89581b4-29c4-4df0-b3b4-f3234e6fd884'	System	07 Aug 2020 22:03:20
User entered 'No (N)'	System	07 Aug 2020 22:03:20

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:11', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f89581b4-29c4-4df0-b3b4-f3234e6fd884'	System	07 Aug 2020 22:03:20
User entered 'No (N)'	System	07 Aug 2020 22:03:20

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-07T18:03:14', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f89581b4-29c4-4df0-b3b4-f3234e6fd884'	System	07 Aug 2020 22:03:20
User entered 'None (1)'	System	07 Aug 2020 22:03:20

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:16', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f89581b4-29c4-4df0-b3b4-f3234e6fd884'	System	07 Aug 2020 22:03:20
User entered '07 Aug 2020 18:03'	System	07 Aug 2020 22:03:20

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 4'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-08T18:05:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '10f2238e-bb1f-43e3-aa40-ade71eff9879'	System	08 Aug 2020 22:05:48
User entered 'None (1)'	System	08 Aug 2020 22:05:48

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '10f2238e-bb1f-43e3-aa40-ade71eff9879'	System	08 Aug 2020 22:05:48
User entered 'No (N)'	System	08 Aug 2020 22:05:48

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '10f2238e-bb1f-43e3-aa40-ade71eff9879'	System	08 Aug 2020 22:05:48
User entered 'No (N)'	System	08 Aug 2020 22:05:48

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-08T18:05:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '10f2238e-bb1f-43e3-aa40-ade71eff9879'	System	08 Aug 2020 22:05:48
User entered 'None (1)'	System	08 Aug 2020 22:05:48

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '10f2238e-bb1f-43e3-aa40-ade71eff9879'	System	08 Aug 2020 22:05:48
User entered '08 Aug 2020 18:05'	System	08 Aug 2020 22:05:48

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 5'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T11:19:10', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '36453c5b-feb1-485c-a5b6-6b6aa3719916'	System	10 Aug 2020 15:19:21
User entered 'None (1)'	System	10 Aug 2020 15:19:21

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:13', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '36453c5b-feb1-485c-a5b6-6b6aa3719916'	System	10 Aug 2020 15:19:21
User entered 'No (N)'	System	10 Aug 2020 15:19:21

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '36453c5b-feb1-485c-a5b6-6b6aa3719916'	System	10 Aug 2020 15:19:21
User entered 'No (N)'	System	10 Aug 2020 15:19:21

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T11:19:16', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '36453c5b-feb1-485c-a5b6-6b6aa3719916'	System	10 Aug 2020 15:19:21
User entered 'None (1)'	System	10 Aug 2020 15:19:21

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '36453c5b-feb1-485c-a5b6-6b6aa3719916'	System	10 Aug 2020 15:19:21
User entered '10 Aug 2020 11:19'	System	10 Aug 2020 15:19:21

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 6'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T17:48:10', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c69e79ab-7b99-432e-9fc3-be3c7c006f79'	System	10 Aug 2020 21:48:25
User entered 'None (1)'	System	10 Aug 2020 21:48:25

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:12', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c69e79ab-7b99-432e-9fc3-be3c7c006f79'	System	10 Aug 2020 21:48:25
User entered 'No (N)'	System	10 Aug 2020 21:48:25

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c69e79ab-7b99-432e-9fc3-be3c7c006f79'	System	10 Aug 2020 21:48:25
User entered 'No (N)'	System	10 Aug 2020 21:48:25

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T17:48:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c69e79ab-7b99-432e-9fc3-be3c7c006f79'	System	10 Aug 2020 21:48:25
User entered 'None (1)'	System	10 Aug 2020 21:48:25

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c69e79ab-7b99-432e-9fc3-be3c7c006f79'	System	10 Aug 2020 21:48:25
User entered '10 Aug 2020 17:48'	System	10 Aug 2020 21:48:25

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 7'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-11T18:02:12', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cec97423-db21-408f-b846-339b7912fb3d'	System	11 Aug 2020 22:02:23
User entered 'None (1)'	System	11 Aug 2020 22:02:23

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cec97423-db21-408f-b846-339b7912fb3d'	System	11 Aug 2020 22:02:23
User entered 'No (N)'	System	11 Aug 2020 22:02:23

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cec97423-db21-408f-b846-339b7912fb3d'	System	11 Aug 2020 22:02:23
User entered 'No (N)'	System	11 Aug 2020 22:02:23

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-11T18:02:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cec97423-db21-408f-b846-339b7912fb3d'	System	11 Aug 2020 22:02:23
User entered 'None (1)'	System	11 Aug 2020 22:02:23

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cec97423-db21-408f-b846-339b7912fb3d'	System	11 Aug 2020 22:02:23
User entered '11 Aug 2020 18:02'	System	11 Aug 2020 22:02:23

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:11', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'None (0)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T09:32:41', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered 'No (N)'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T09:32:44', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9edb22c7-d660-4428-a3df-ac7ed1caf8fb'	System	05 Aug 2020 13:32:47
User entered '05 Aug 2020 09:32'	System	05 Aug 2020 13:32:47

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:15'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:45'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:07', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:13', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:20', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:22', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:24', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'None (0)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-05T18:13:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered 'No (N)'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-05T18:13:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2498be67-147d-4304-b6af-045b2694f54a'	System	05 Aug 2020 22:13:51
User entered '05 Aug 2020 18:13'	System	05 Aug 2020 22:13:51

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:40'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 2'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:13', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:22', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:24', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'None (0)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-06T18:04:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f'	System	06 Aug 2020 22:04:34
User entered 'No (N)'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-06T18:04:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '5f06022d-c7e9-402c-a8fb-5ce57feb0a7f' User entered '06 Aug 2020 18:04'	System	06 Aug 2020 22:04:34
	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 3'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:24', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'None (0)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-07T18:03:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered 'No (N)'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-07T18:03:41', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '89598f7b-dd7e-43a3-9c29-7f16a6ed91f0'	System	07 Aug 2020 22:03:45
User entered '07 Aug 2020 18:03'	System	07 Aug 2020 22:03:45

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 4'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:49', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:54', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:56', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:05:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'None (0)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-08T18:06:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered 'No (N)'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-08T18:06:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd7241123-0960-4817-9cf7-90312713077e'	System	08 Aug 2020 22:06:04
User entered '08 Aug 2020 18:06'	System	08 Aug 2020 22:06:04

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 5'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:24', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'None (0)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T11:19:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered 'No (N)'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T11:19:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd8ab1c2b-dfb2-4a5c-a99c-7dcb9b0e6b22'	System	10 Aug 2020 15:19:41
User entered '10 Aug 2020 11:19'	System	10 Aug 2020 15:19:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 6'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:31', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'None (0)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-10T17:48:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered 'No (N)'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-10T17:48:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8122d7b7-3dd1-4223-8685-d1ded97bc8aa'	System	10 Aug 2020 21:48:41
User entered '10 Aug 2020 17:48'	System	10 Aug 2020 21:48:41

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 7'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:25', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:31', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'None (0)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-08-11T18:02:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered 'No (N)'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-08-11T18:02:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '645339de-d076-4b7e-b694-95d558fbd498'	System	11 Aug 2020 22:02:38
User entered '11 Aug 2020 18:02'	System	11 Aug 2020 22:02:38

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:26

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 22:19:11

US3412127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:19:11

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 19:02:03
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	17 Sep 2020 19:02:03
User entered '19 Aug 2020' reason for change: Data Entry Error	Mason Urban (b) (4)	17 Sep 2020 19:02:03
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 19:01:23
User entered '17 Sep 2020'	Mason Urban (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 22:19:21

US3412127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:19:21

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 22:19:37

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:19:37

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '17:25'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:25'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '14'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '70'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '18:48'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:48'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '12'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '80'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:23:07

US3412127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:23:07

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '18:17'	(b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:17'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '17:40'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:40'	System	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '17:43'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:43'	System	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:29:36

US3412127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:29:36

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '361626eb-df75-46ef-992e-ee3c9e596579'	System	03 Sep 2020 22:51:49
User entered 'Yes (Y)'	System	03 Sep 2020 22:51:49

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '361626eb-df75-46ef-992e-ee3c9e596579'	System	03 Sep 2020 22:51:49
User entered '97.8'	System	03 Sep 2020 22:51:49

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '361626eb-df75-46ef-992e-ee3c9e596579'	System	03 Sep 2020 22:51:49
User entered 'No (N)'	System	03 Sep 2020 22:51:49

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:46', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '361626eb-df75-46ef-992e-ee3c9e596579'	System	03 Sep 2020 22:51:49
User entered '03 Sep 2020 18:51'	System	03 Sep 2020 22:51:49

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 21:07'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:02:52', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3bde722a-6c57-4145-b464-bb7e44c1691a'	System	04 Sep 2020 10:04:01
User entered 'Yes (Y)'	System	04 Sep 2020 10:04:01

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:03:50', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3bde722a-6c57-4145-b464-bb7e44c1691a'	System	04 Sep 2020 10:04:01
User entered '98.3'	System	04 Sep 2020 10:04:01

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:03:54', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3bde722a-6c57-4145-b464-bb7e44c1691a'	System	04 Sep 2020 10:04:01
User entered 'No (N)'	System	04 Sep 2020 10:04:01

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:03:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3bde722a-6c57-4145-b464-bb7e44c1691a'	System	04 Sep 2020 10:04:01
User entered '04 Sep 2020 06:03'	System	04 Sep 2020 10:04:01

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 22:02'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 2'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:43:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '54594376-2fa0-4101-87e4-5a22dfb12b12'	System	04 Sep 2020 19:43:16
User entered 'Yes (Y)'	System	04 Sep 2020 19:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:43:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '54594376-2fa0-4101-87e4-5a22dfb12b12'	System	04 Sep 2020 19:43:16
User entered '98.5'	System	04 Sep 2020 19:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:43:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '54594376-2fa0-4101-87e4-5a22dfb12b12'	System	04 Sep 2020 19:43:16
User entered 'No (N)'	System	04 Sep 2020 19:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:43:10', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '54594376-2fa0-4101-87e4-5a22dfb12b12'	System	04 Sep 2020 19:43:16
User entered '04 Sep 2020 15:43'	System	04 Sep 2020 19:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 3'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:09:01', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4b537224-7062-4b58-83e9-b69869713320'	System	05 Sep 2020 16:09:14
User entered 'Yes (Y)'	System	05 Sep 2020 16:09:14

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:09:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4b537224-7062-4b58-83e9-b69869713320'	System	05 Sep 2020 16:09:14
User entered '98.3'	System	05 Sep 2020 16:09:14

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:09:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4b537224-7062-4b58-83e9-b69869713320'	System	05 Sep 2020 16:09:14
User entered 'No (N)'	System	05 Sep 2020 16:09:14

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:09:11', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4b537224-7062-4b58-83e9-b69869713320'	System	05 Sep 2020 16:09:14
User entered '05 Sep 2020 12:09'	System	05 Sep 2020 16:09:14

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 4'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:42:49', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4ff7913b-d42a-4c12-999a-323bf4ba83cd'	System	06 Sep 2020 17:43:04
User entered 'Yes (Y)'	System	06 Sep 2020 17:43:04

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:42:54', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4ff7913b-d42a-4c12-999a-323bf4ba83cd'	System	06 Sep 2020 17:43:04
User entered '98.0'	System	06 Sep 2020 17:43:04

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:42:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4ff7913b-d42a-4c12-999a-323bf4ba83cd'	System	06 Sep 2020 17:43:04
User entered 'No (N)'	System	06 Sep 2020 17:43:04

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4ff7913b-d42a-4c12-999a-323bf4ba83cd'	System	06 Sep 2020 17:43:04
User entered '06 Sep 2020 13:43'	System	06 Sep 2020 17:43:04

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 5'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '0ff907d3-494d-4c1a-8d8a-7702ac5c8f40'	System	07 Sep 2020 19:32:45
User entered 'Yes (Y)'	System	07 Sep 2020 19:32:45

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '0ff907d3-494d-4c1a-8d8a-7702ac5c8f40'	System	07 Sep 2020 19:32:45
User entered '98.3'	System	07 Sep 2020 19:32:45

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '0ff907d3-494d-4c1a-8d8a-7702ac5c8f40'	System	07 Sep 2020 19:32:45
User entered 'No (N)'	System	07 Sep 2020 19:32:45

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:42', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '0ff907d3-494d-4c1a-8d8a-7702ac5c8f40'	System	07 Sep 2020 19:32:45
User entered '07 Sep 2020 15:32'	System	07 Sep 2020 19:32:45

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 6'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cb6fd0a7-966d-4687-be4f-d09841531fdd'	System	09 Sep 2020 09:26:19
User entered 'Yes (Y)'	System	09 Sep 2020 09:26:19

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:11', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cb6fd0a7-966d-4687-be4f-d09841531fdd'	System	09 Sep 2020 09:26:19
User entered '97.9'	System	09 Sep 2020 09:26:19

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:14', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cb6fd0a7-966d-4687-be4f-d09841531fdd'	System	09 Sep 2020 09:26:19
User entered 'No (N)'	System	09 Sep 2020 09:26:19

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'cb6fd0a7-966d-4687-be4f-d09841531fdd'	System	09 Sep 2020 09:26:19
User entered '09 Sep 2020 05:26'	System	09 Sep 2020 09:26:19

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 7'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7d0617ab-87e6-4312-a1fd-a141e99c7453'	System	09 Sep 2020 21:57:30
User entered 'Yes (Y)'	System	09 Sep 2020 21:57:30

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:25', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7d0617ab-87e6-4312-a1fd-a141e99c7453'	System	09 Sep 2020 21:57:30
User entered '98.4'	System	09 Sep 2020 21:57:30

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7d0617ab-87e6-4312-a1fd-a141e99c7453'	System	09 Sep 2020 21:57:30
User entered 'No (N)'	System	09 Sep 2020 21:57:30

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '7d0617ab-87e6-4312-a1fd-a141e99c7453'	System	09 Sep 2020 21:57:30
User entered '09 Sep 2020 17:57'	System	09 Sep 2020 21:57:30

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-03T18:51:52', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f1937a85-3e92-444e-bc64-a4910f5e5852'	System	03 Sep 2020 22:52:11
User entered 'None (1)'	System	03 Sep 2020 22:52:11

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f1937a85-3e92-444e-bc64-a4910f5e5852'	System	03 Sep 2020 22:52:11
User entered 'No (N)'	System	03 Sep 2020 22:52:11

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:51:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f1937a85-3e92-444e-bc64-a4910f5e5852'	System	03 Sep 2020 22:52:11
User entered 'No (N)'	System	03 Sep 2020 22:52:11

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-03T18:52:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f1937a85-3e92-444e-bc64-a4910f5e5852'	System	03 Sep 2020 22:52:11
User entered 'None (1)'	System	03 Sep 2020 22:52:11

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:09', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f1937a85-3e92-444e-bc64-a4910f5e5852'	System	03 Sep 2020 22:52:11
User entered '03 Sep 2020 18:52'	System	03 Sep 2020 22:52:11

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 21:07'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[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 (c45938ec87da2c96)', Time: '2020-09-04T06:04:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:04:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered 'No (N)'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:04:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered 'Yes (Y)'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered '4'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-04T06:05:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered 'None (1)'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74fff6c1-7f98-49f9-b9d8-02f20ba0a2c1'	System	04 Sep 2020 10:05:41
User entered '04 Sep 2020 06:05'	System	04 Sep 2020 10:05:41

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 22:02'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 2'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-04T15:42:11', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:14', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered 'No (N)'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered 'Yes (Y)'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:20', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered '4'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-04T15:42:25', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered 'None (1)'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '9d728703-3b68-4709-9ff6-f8f7680fb1c7'	System	04 Sep 2020 19:42:31
User entered '04 Sep 2020 15:42'	System	04 Sep 2020 19:42:31

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 3'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[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 (c45938ec87da2c96)', Time: '2020-09-05T12:09:16', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '364a9fde-971c-45de-a84b-9b0621149279'	System	05 Sep 2020 16:10:23
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 16:10:23

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '364a9fde-971c-45de-a84b-9b0621149279'	System	05 Sep 2020 16:10:23
User entered 'No (N)'	System	05 Sep 2020 16:10:23

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '364a9fde-971c-45de-a84b-9b0621149279'	System	05 Sep 2020 16:10:23
User entered 'No (N)'	System	05 Sep 2020 16:10:23

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-05T12:10:18', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '364a9fde-971c-45de-a84b-9b0621149279'	System	05 Sep 2020 16:10:23
User entered 'None (1)'	System	05 Sep 2020 16:10:23

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:20', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '364a9fde-971c-45de-a84b-9b0621149279'	System	05 Sep 2020 16:10:23
User entered '05 Sep 2020 12:10'	System	05 Sep 2020 16:10:23

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 4'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[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 (c45938ec87da2c96)', Time: '2020-09-06T13:43:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21498ea3-757b-40c4-874e-6b17a804c9dc'	System	06 Sep 2020 17:43:16
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 17:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:08', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21498ea3-757b-40c4-874e-6b17a804c9dc'	System	06 Sep 2020 17:43:16
User entered 'No (N)'	System	06 Sep 2020 17:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:10', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21498ea3-757b-40c4-874e-6b17a804c9dc'	System	06 Sep 2020 17:43:16
User entered 'No (N)'	System	06 Sep 2020 17:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-06T13:43:13', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21498ea3-757b-40c4-874e-6b17a804c9dc'	System	06 Sep 2020 17:43:16
User entered 'None (1)'	System	06 Sep 2020 17:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21498ea3-757b-40c4-874e-6b17a804c9dc'	System	06 Sep 2020 17:43:16
User entered '06 Sep 2020 13:43'	System	06 Sep 2020 17:43:16

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 5'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-07T15:32:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '94ff97b5-1dfe-428a-8da4-0fbbee1dc922'	System	07 Sep 2020 19:32:58
User entered 'None (1)'	System	07 Sep 2020 19:32:58

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '94ff97b5-1dfe-428a-8da4-0fbbee1dc922'	System	07 Sep 2020 19:32:58
User entered 'No (N)'	System	07 Sep 2020 19:32:58

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '94ff97b5-1dfe-428a-8da4-0fbbee1dc922'	System	07 Sep 2020 19:32:58
User entered 'No (N)'	System	07 Sep 2020 19:32:58

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-07T15:32:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '94ff97b5-1dfe-428a-8da4-0fbbee1dc922'	System	07 Sep 2020 19:32:58
User entered 'None (1)'	System	07 Sep 2020 19:32:58

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:56', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '94ff97b5-1dfe-428a-8da4-0fbbee1dc922'	System	07 Sep 2020 19:32:58
User entered '07 Sep 2020 15:32'	System	07 Sep 2020 19:32:58

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 6'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-09T05:26:22', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a46a718-7f26-463f-8179-025f9fe9e141'	System	09 Sep 2020 09:26:35
User entered 'None (1)'	System	09 Sep 2020 09:26:35

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:25', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a46a718-7f26-463f-8179-025f9fe9e141'	System	09 Sep 2020 09:26:35
User entered 'No (N)'	System	09 Sep 2020 09:26:35

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a46a718-7f26-463f-8179-025f9fe9e141'	System	09 Sep 2020 09:26:35
User entered 'No (N)'	System	09 Sep 2020 09:26:35

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[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 (c45938ec87da2c96)', Time: '2020-09-09T05:26:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a46a718-7f26-463f-8179-025f9fe9e141'	System	09 Sep 2020 09:26:35
User entered 'None (1)'	System	09 Sep 2020 09:26:35

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a46a718-7f26-463f-8179-025f9fe9e141'	System	09 Sep 2020 09:26:35
User entered '09 Sep 2020 05:26'	System	09 Sep 2020 09:26:35

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 7'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-09T17:57:46', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '6cc8e040-013a-463d-8b63-f8702fd2bf3f'	System	09 Sep 2020 21:57:54
User entered 'None (1)'	System	09 Sep 2020 21:57:54

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '6cc8e040-013a-463d-8b63-f8702fd2bf3f'	System	09 Sep 2020 21:57:54
User entered 'No (N)'	System	09 Sep 2020 21:57:54

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:49', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '6cc8e040-013a-463d-8b63-f8702fd2bf3f'	System	09 Sep 2020 21:57:54
User entered 'No (N)'	System	09 Sep 2020 21:57:54

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-09T17:57:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '6cc8e040-013a-463d-8b63-f8702fd2bf3f'	System	09 Sep 2020 21:57:54
User entered 'None (1)'	System	09 Sep 2020 21:57:54

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '6cc8e040-013a-463d-8b63-f8702fd2bf3f'	System	09 Sep 2020 21:57:54
User entered '09 Sep 2020 17:57'	System	09 Sep 2020 21:57:54

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:16', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'None (0)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-03T18:52:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered 'No (N)'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-03T18:52:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '430593d6-cf4e-40d0-958d-1f69bde175b8'	System	03 Sep 2020 22:52:41
User entered '03 Sep 2020 18:52'	System	03 Sep 2020 22:52:41

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:37'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 21:07'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:47', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:05:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'None (0)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-04T06:06:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered 'No (N)'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T06:06:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '18eec7d7-431a-498f-9822-384536371b86'	System	04 Sep 2020 10:06:04
User entered '04 Sep 2020 06:06'	System	04 Sep 2020 10:06:04

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 22:02'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 2'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'Some interference with activity (2)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'None (0)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:50', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'None (0)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-04T15:42:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered 'No (N)'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-04T15:42:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8d392f15-4108-40c3-aef0-9e594d2914bf'	System	04 Sep 2020 19:42:58
User entered '04 Sep 2020 15:42'	System	04 Sep 2020 19:42:58

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 3'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'None (0)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-05T12:10:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered 'No (N)'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-05T12:10:42', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8ea0b344-7e2d-4d7a-92ab-1129ad37261c'	System	05 Sep 2020 16:10:45
User entered '05 Sep 2020 12:10'	System	05 Sep 2020 16:10:45

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 4'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'None (0)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-06T13:43:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered 'No (N)'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-06T13:43:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8f374376-fffd-497e-8915-a4a4c34c8841'	System	06 Sep 2020 17:43:40
User entered '06 Sep 2020 13:43'	System	06 Sep 2020 17:43:40

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 5'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:32:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:01', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:03', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'None (0)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-07T15:33:07', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered 'No (N)'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-07T15:33:09', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '55948855-e132-496f-9b38-4ad68402b49b'	System	07 Sep 2020 19:33:12
User entered '07 Sep 2020 15:33'	System	07 Sep 2020 19:33:12

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 6'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:36', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:42', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'None (0)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-09T05:26:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered 'No (N)'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T05:26:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '256ae6ed-5b2d-43cb-a6a9-cf0544151a16'	System	09 Sep 2020 09:26:49
User entered '09 Sep 2020 05:26'	System	09 Sep 2020 09:26:49

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 22:21:17
User entered 'Day 7'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:32', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'None (0)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

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 (c45938ec87da2c96)', Time: '2020-09-09T17:57:41', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered 'No (N)'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-09-09T17:57:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '53e1053f-61ac-4bf5-8ddc-c707c4f290fb'	System	09 Sep 2020 21:57:47
User entered '09 Sep 2020 17:57'	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 22:21:17

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 22:21:17

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:29:58

US3412127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:29:58

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	17 Sep 2020 19:02:16

US3412127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 19:02:16

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Mason Urban (b) (4) (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	25 Sep 2020 18:15:26

US3412127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 18:15:26

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 17:02:19

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:05:35
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:40

US3412127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:05:35
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 17:03:17
User entered '02 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 17:03:17
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 17:02:40
User entered '02 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:02:40

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '12:31'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:31'	System	02 Oct 2020 17:05:07

US3412127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:05:15
	(b) (4)	

US3412127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 17:05:15

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 64'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-09T18:46:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3176340b-084f-4ce7-9356-f18a0a95cf20'	System	09 Oct 2020 22:46:51
User entered 'No (N)'	System	09 Oct 2020 22:46:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-09T18:46:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3176340b-084f-4ce7-9356-f18a0a95cf20'	System	09 Oct 2020 22:46:51
User entered 'No (N)'	System	09 Oct 2020 22:46:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-09T18:46:51', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3176340b-084f-4ce7-9356-f18a0a95cf20'	System	09 Oct 2020 22:46:51
User entered '09 Oct 2020 18:46:51'	System	09 Oct 2020 22:46:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 71'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-15T18:03:13', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '19033aed-4553-4907-9846-f24ce0398bc2'	System	15 Oct 2020 22:03:29
User entered 'No (N)'	System	15 Oct 2020 22:03:29

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-15T18:03:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '19033aed-4553-4907-9846-f24ce0398bc2'	System	15 Oct 2020 22:03:29
User entered 'No (N)'	System	15 Oct 2020 22:03:29

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-15T18:03:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '19033aed-4553-4907-9846-f24ce0398bc2'	System	15 Oct 2020 22:03:29
User entered '15 Oct 2020 18:03:27'	System	15 Oct 2020 22:03:29

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 78'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-23T06:22:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c46d8766-c98d-4178-a767-f3b40d43ce7b'	System	23 Oct 2020 10:22:56
User entered 'No (N)'	System	23 Oct 2020 10:22:56

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-23T06:22:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c46d8766-c98d-4178-a767-f3b40d43ce7b'	System	23 Oct 2020 10:22:56
User entered 'No (N)'	System	23 Oct 2020 10:22:56

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-10-23T06:22:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c46d8766-c98d-4178-a767-f3b40d43ce7b' User entered '23 Oct 2020 06:22:43'	System	23 Oct 2020 10:22:56
	System	23 Oct 2020 10:22:56

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 92'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-06T09:25:35', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21f93216-ca56-44bd-a9d9-59d45fabb97c'	System	06 Nov 2020 14:25:44
User entered 'No (N)'	System	06 Nov 2020 14:25:44

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-06T09:25:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21f93216-ca56-44bd-a9d9-59d45fabb97c'	System	06 Nov 2020 14:25:44
User entered 'No (N)'	System	06 Nov 2020 14:25:44

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-06T09:25:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '21f93216-ca56-44bd-a9d9-59d45fabb97c'	System	06 Nov 2020 14:25:44
User entered '06 Nov 2020 09:25:40'	System	06 Nov 2020 14:25:44

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 99'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-13T18:30:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e3ce8b10-c4f2-4a60-843c-b58b171f8752'	System	13 Nov 2020 23:30:47
User entered 'No (N)'	System	13 Nov 2020 23:30:47

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-13T18:30:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e3ce8b10-c4f2-4a60-843c-b58b171f8752'	System	13 Nov 2020 23:30:47
User entered 'No (N)'	System	13 Nov 2020 23:30:47

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-13T18:30:43', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'e3ce8b10-c4f2-4a60-843c-b58b171f8752'	System	13 Nov 2020 23:30:47
User entered '13 Nov 2020 18:30:43'	System	13 Nov 2020 23:30:47

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 12:59:26

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Oct 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Oct 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-23T06:15:00', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f089544a-21ff-4948-9401-ac8934d9697c'	System	23 Nov 2020 11:15:09
User entered 'No (N)'	System	23 Nov 2020 11:15:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-23T06:15:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f089544a-21ff-4948-9401-ac8934d9697c'	System	23 Nov 2020 11:15:09
User entered 'No (N)'	System	23 Nov 2020 11:15:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-23T06:15:05', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f089544a-21ff-4948-9401-ac8934d9697c'	System	23 Nov 2020 11:15:09
User entered '23 Nov 2020 06:15:05'	System	23 Nov 2020 11:15:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:06:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:06:51
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 06:58:26
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'this is the correct date. site was unable to be reached prior to this.' (Site from System).	Steven Anderson (b) (4)	12 Nov 2020 18:47:25
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Nov 2020 16:46:59
User entered '2 Nov 2020'	Mason Urban (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Nov 2020 16:47:07

US3412127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 16:47:07

US3412127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 19:39:47

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:04:21
User entered 'USA-US061-2020-mRNA-1273-P301000001'	System	18 Aug 2020 13:03:59
User entered 'New'	(b) (4), (b) (6)	18 Aug 2020 13:03:59

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'Per MM, please confirm if the patient was evaluated for SARS-CoV-2 infection.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:02:45
Query 'Per MM, please confirm if the patient was evaluated for SARS-CoV-2 infection.' answered with 'this subject was evaluated for SARS-CoV-2 and tested negative' (Site from DM).	Steven Anderson (b) (4)	14 Oct 2020 13:54:40
User opened query 'Per MM, please confirm if the patient was evaluated for SARS-CoV-2 infection.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:54:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 17:12:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 17:12:46
Data point term sent to Coder	System	23 Sep 2020 17:11:11
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 17:10:35
User entered 'Acute Respiratory Failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 17:10:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:19:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:19:16
Data point term sent to Coder	System	17 Aug 2020 20:18:03
User entered 'Upper Respiratory Tract Infection'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 17:59:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 17:59:47
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:59:47
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:00:51
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 15:00:51
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 10:38:40
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	03 Sep 2020 22:21:17
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'Per CDM: Please remove the data 00:00 and leave the field blank as the AE started after 24 hours of dosing.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:31:41
Query 'Per CDM: Please remove the data 00:00 and leave the field blank as the AE started after 24 hours of dosing.' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4)	14 Oct 2020 13:56:07
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 13:54:58
User opened query 'Per CDM: Please remove the data 00:00 and leave the field blank as the AE started after 24 hours of dosing.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:14:10
Query 'Per CDM, Start time is required only for an AE that start within 24 hours after dosing. Please review Start Date/Start time again and remove start time (leave field blank) if AE indeed not started within 24 hours after dosing. Otherwise provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:45:04
User opened query 'Per CDM, Start time is required only for an AE that start within 24 hours after dosing. Please review Start Date/Start time again and remove start time (leave field blank) if AE indeed not started within 24 hours after dosing. Otherwise provide explanation.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 13:48:29
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 18:37:28
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'error' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:51:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 20:51:42
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 20:51:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 20:17:31
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	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 13:54:58
User entered '14 Aug 2020 00:00'	System	17 Aug 2020 20:51:42
User entered '14 Aug 2020 UN:UN' (non-conformant).	System	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:59:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:07
Query 'PV Query: Please provide the event end date, when available.' answered with '20 AUG 2020 ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:00:19
User entered '20 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:59:47
User opened query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 16:01:46
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'PV 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 Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:22
Query 'PV Query: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3.' answered with 'AS PER PROTOCOL HOSP ADMISSIONS ARE GRADE 4 ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:00:05
User opened query 'PV 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 Safety).	(b) (4), (b) (6)	19 Aug 2020 16:01:13
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
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).	(b) (4), (b) (6)	18 Aug 2020 18:37:55
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 with 'hospital admission date is entered' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:52:32
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	17 Aug 2020 20:17:31
User entered '1'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '16 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:27
Query 'PV Query: Please provide the hospital discharge date when available.' answered with '20 AUG 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:00:37
User entered '20 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:59:47
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 16:01:32
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
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	17 Aug 2020 20:52:47
Query 'Admitted to ICU? is Unknown. However, this System 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).		17 Aug 2020 20:52:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 20:52:47
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	17 Aug 2020 20:17:31
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
Query 'Per ETRTR: No medication found within CRF page for Con Meds, please confirm response or update CRF as applicable, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:44:24
User opened query 'Per ETRTR: No medication found within CRF page for Con Meds, please confirm response or update CRF as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 16:35:31
User entered '1'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:35
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'RESOLVED ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:00:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:59:47
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 16:02:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'please update narrative with all pertinent details' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:21
	(b) (4), (b) (6)	07 Nov 2020 02:57:08
Query 'please update narrative with all pertinent details' answered with 'the narrative has been updated from the subjects discharge summary' (Site from CRA).	Steven Anderson (b) (4)	14 Oct 2020 14:01:04
User entered 'Subject US3412127 was admitted for acute respiratory failure and suspected respiratory infection. infectious disease consulted. He was treated with levaquin and solumedrol. he improved accordingly. Patient was tested for COVID-19 and remained negative.' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 14:00:11
User opened query 'please update narrative with all pertinent details' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 00:07:04
User closed query 'PV Query: Please confirm the cause of the acute respiratory failure (ex-lower respiratory tract infection?) and consider reporting this as SAE. ' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:54:19
User closed 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)	02 Oct 2020 12:54:16
User closed query 'PV Query: Please provide vital signs and physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:54:13
User closed query 'PV Query: Did the subject require supplemental oxygen?' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:54:08
User closed query 'PV Query: Please provide results of lab/diagnostic tests performed in evaluation of the event (i.e. chest x-ray, ABG, pulse oximetry, WBC, CRP, cultures, etc)' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:54:05

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[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 'hospital Discharge papers fax has been sent at 2:01pm on 01 oct 2020 ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 18:01:58
Query 'PV Query: Please confirm the cause of the acute respiratory failure (ex-lower respiratory tract infection?) and consider reporting this as SAE. ' answered with 'FINAL DIAGNOSIS RESPIRATORY INFECTION ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 15:07:37
Query 'PV Query: Please provide vital signs and physical exam findings.' answered with 'ON DISCHARGE DAY VIATLS: BP: 112/66, PULSE: 86, TEMP: 98.6F ORAL, RR: 16, SPO2: 94, BMI: 25.06 KG/M2 ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 15:06:35
Query 'PV Query: Did the subject require supplemental oxygen?' answered with 'NASAL CANNUAL ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 15:02:16
Query 'PV Query: Please provide results of lab/diagnostic tests performed in evaluation of the event (i.e. chest x-ray, ABG, pulse oximetry, WBC, CRP, cultures, etc)' answered with 'THE FOLLOWING WERE ELEVATED: WBC 14.3, NEUT 11.5, D-DIMER 322, SED RATE 23.FOLLOWING ARE LOW: TC02 20, BASE EXCESS -2.1. THE CHEST XRAY HAD NO ACUTE FINDINGS. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:59:23
User opened query 'PV Query: Please confirm the cause of the acute respiratory failure (ex-lower respiratory tract infection?) and consider reporting this as SAE. ' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:21:29
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)	29 Sep 2020 16:21:05
User opened query 'PV Query: Please provide vital signs and physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:18:33

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject require supplemental oxygen?' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:18:25
User opened query 'PV Query: Please provide results of lab/diagnostic tests performed in evaluation of the event (i.e. chest x-ray, ABG, pulse oximetry, WBC, CRP, cultures, etc)' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 16:18:18
User closed query 'PV Query: Please provide the results from the repeat COVID-19 test performed on 20 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:48
User closed query 'PV Query: Please provide the date the Negative COVID-19 test was performed prior to the hospitalization' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:46
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:18:42
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)	20 Sep 2020 20:18:39
Query 'PV Query: Please provide the date the Negative COVID-19 test was performed prior to the hospitalization' answered with '05 AUG 2020 NASO SWAB TEST RESULTS NEGATIVE ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:58:02
Query 'PV Query: Please provide the results from the repeat COVID-19 test performed on 20 Aug 2020.' answered with 'NEGATIVE ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:56:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ALBUTEROL LEVOFLOXACIN PREDNISONE ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:56:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'COVID-19 TESTED NEGATIVE ON 20 AUG 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 17:55:33
User opened query 'PV Query: Please provide the date the Negative COVID-19 test was performed prior to the hospitalization' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:00:23
User opened query 'PV Query: Please provide the results from the repeat COVID-19 test performed on 20 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:00:10
Query 'PV Query: Was the subject tested for COVID-19 before and after the symptoms of URI appeared?' canceled (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 14:59:58
Query 'PV Query: Please confirm if the subject had a nasopharyngeal swab or respiratory sample collected to test for Covid-19 while hospitalized. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 14:59:12
User opened query 'PV Query: Please confirm if the subject had a nasopharyngeal swab or respiratory sample collected to test for Covid-19 while hospitalized. ' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 19:37:26
User opened query 'PV Query: Was the subject tested for COVID-19 before and after the symptoms of URI appeared?' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 16:02:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Aug 2020 16:02:26
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)	19 Aug 2020 16:02:14
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Aug 2020 20:55:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 20:55:26
User entered 'subject was hospitalized 16aug2020 with congestion, dry cough, fever and shortness of breath' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 20:55:26
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Aug 2020 20:17:31
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 02:09:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:09:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 02:09:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:20:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:23:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:23:27
Data point term sent to Coder	System	14 Aug 2020 17:22:17
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 13:00:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:21:29
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:21:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:23:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:23:27
Data point term sent to Coder	System	14 Aug 2020 17:22:18
User entered 'TRINTELLIX'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'PTSD'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 13:00:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:22:05
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:05:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:05:13
Data point term sent to Coder	System	14 Aug 2020 17:23:20
User entered 'WELLBUTRIN'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'PTSD'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '300'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 13:00:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:22:37
User entered 'UN UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:25:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:25:03
Data point term sent to Coder Coding entries removed.	System Jacob sekinger (b) (4) (b) (4)	27 Oct 2020 17:37:40 27 Oct 2020 17:37:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:18:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:18:21
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4) (b) (4)	14 Oct 2020 14:51:03 14 Oct 2020 14:50:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:25:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:25:16
Data point term sent to Coder	System	14 Aug 2020 17:24:26

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'IBUPROFEN'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User closed query 'Per DM CLR: Please update type of SOLICITE PAIN (e.g. INJECTION SITE PAIN, MUSCLE ACHES ALL OVER BODY etc.). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:01:58
Query 'Per DM CLR: Please update type of SOLICITE PAIN (e.g. INJECTION SITE PAIN, MUSCLE ACHES ALL OVER BODY etc.). Update as appropriate.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4)	27 Oct 2020 17:37:45
User entered 'SOLICITED PAIN - myalgia and joint aches' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 17:37:39
User opened query 'Per DM CLR: Please update type of SOLICITE PAIN (e.g. INJECTION SITE PAIN, MUSCLE ACHES ALL OVER BODY etc.). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:01:01
User closed 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 ensure to include the type and location of PAIN and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:01:01
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 ensure to include the type and location of PAIN and all applicable details to the appropriate MH or AE eCRF.' answered with 'this is not MH condition this is was used for solicited AE pain' (Site from DM).	Steven Anderson (b) (4)	14 Oct 2020 14:56:26
User entered 'Solicited PAIN' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 14:50:59
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 ensure to include the type and location of PAIN and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:30:09

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[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)	06 Oct 2020 05:29:56
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)	06 Oct 2020 05:29:46
User entered 'PAIN'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '800'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '06 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 14:55:53
User entered '05 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 14:55:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:41:40
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:10:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '06 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Oct 2020 14:55:53
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:41:40
User entered '20 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:10:47
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SOLICITED PAIN - MYALGIA AND JOINT ACHES in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'In diary day 1, temperature day, the subject reports taking medication on this day. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	20 Nov 2020 15:49:47
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SOLICITED PAIN - MYALGIA AND JOINT ACHES in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Nov 2020 08:18:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	10 Nov 2020 22:07:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	14 Oct 2020 14:55:53
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:56:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:56:45
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 17:16:17 23 Sep 2020 17:15:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:13:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:13:37
Data point term sent to Coder	System	18 Sep 2020 18:12:38
Data point term sent to Coder	System	18 Sep 2020 18:06:20
User entered 'ALBUTEROL'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 17:15:20
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Mylene Asmar-Rios	18 Sep 2020 18:11:38
User entered 'ACUTE RESPIRATORY FAILURE'	(b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff 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)	05 Nov 2020 16:02:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4)	27 Oct 2020 17:41:30
User entered '90' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 17:41:21
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff 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 10:58:30
User entered '2'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'ug (ug)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 17:41:21
User entered 'puff (PUFF)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'four times daily (QID)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '16 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:43:41
User entered '17 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:19:02
User entered '20 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 17:15:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios	18 Sep 2020 18:43:41
User entered 'No (N)'	(b) (4)	18 Sep 2020 18:06:07
	Mylene Asmar-Rios	
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 17:15:20
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:43:41
User entered '17 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:19:02
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:45:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:45:45
Data point term sent to Coder	System	18 Sep 2020 18:20:52
Data point term sent to Coder	System	18 Sep 2020 18:07:26
User entered 'LEVOFLOXACIN'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:02:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'there is an AE documented for this indication. please see AE folder.' (Site from DM).	Jacob sekinger (b) (4)	27 Oct 2020 17:47:21
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:02:08
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:20:05
User entered 'ACUTE RESPIRATORY FAILURE'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '500'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '16 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:44:14
User entered '17 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:20:05
User entered '20 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios	18 Sep 2020 18:44:14
User entered 'No (N)'	(b) (4)	
	Mylene Asmar-Rios	18 Sep 2020 18:07:19
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:44:14
User entered '22 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:20:05
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 18:07:19

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:32:59
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 Sep 2020 11:32:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:53:38 23 Sep 2020 21:52:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:47:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:47:36
Data point term sent to Coder	System	18 Sep 2020 18:47:01
Data point term sent to Coder	System	18 Sep 2020 18:23:57
Data point term sent to Coder	System	18 Sep 2020 18:08:31
User entered 'PREDNISONE'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:52:56
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Mylene Asmar-Rios	18 Sep 2020 18:23:13
User entered 'ACUTE RESPIRATORY FAILURE'	(b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '40' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:46:15
User entered '60' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:23:13
User entered '40'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)' reason for change:	Myelene Asmar-Rios	18 Sep 2020 18:46:15
Data Entry Error	(b) (4)	
User entered 'four times daily (QID)' reason for change: Data Entry Error	Myelene Asmar-Rios	18 Sep 2020 18:23:13
User entered 'once daily (QD)'	(b) (4)	
	Myelene Asmar-Rios	18 Sep 2020 18:08:29
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:46:15
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:23:13
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:46:15
User entered '17 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:23:13
User entered '20 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:46:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:23:13
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '24 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:46:15
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:23:13
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:46:15
User entered '4'	System	18 Sep 2020 18:23:13
User entered '1'	System	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:46:15
User entered '1'	System	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:46:15
User entered '804 (804)'	System	18 Sep 2020 18:08:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 21:55:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 21:55:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:54:39 23 Sep 2020 21:54:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:29:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:29:44
Data point term sent to Coder User entered 'MUCINEX'	System Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:29:11 18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:54:23
User entered 'UPPER RSPIRATORY INFECTION'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
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)	05 Nov 2020 16:03:06
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.' (Site from DM).	Jacob sekinger (b) (4)	27 Oct 2020 17:45:28
User entered '600' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 17:45:21
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 11:02:38
User entered '1'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 17:45:21
User entered 'tablet (TABLET)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:54:23
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '24 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:54:23
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:28:49

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:12:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:12:58
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:56:43 23 Sep 2020 21:55:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:19:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:19:45
Data point term sent to Coder User entered 'SOLUMEDROL'	System Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:32 18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:55:50
User entered 'UPPER RESPIRATORY INFECTION'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '60'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'four times daily (QID)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:55:50
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:55:50
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 18:34:00

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:48:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:48:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:57:44 23 Sep 2020 21:57:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:34:43
Data point term sent to Coder User entered 'ONDANSTERON'	System Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:36:36 18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:57:09
User entered 'UPPER RESPIRATORY INFECTION'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '4'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)' reason for change:	Mylene Asmar-Rios	18 Sep 2020 18:47:53
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Mylene Asmar-Rios	18 Sep 2020 18:35:37
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:47:53
User entered 'EVERY 6 HOURS'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:57:09
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:57:09
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:19:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:19:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 11:12:57
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 Sep 2020 11:12:57
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:58:46 23 Sep 2020 21:58:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:20:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:20:45
Data point term sent to Coder User entered 'SODIUM CHLORIDE'	System Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:42 18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:58:11
User entered 'UPPER RESPIRATORY INFECTION'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0.9'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'PERCENT'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:58:11
User entered 'Yes (Y)'	Mylene Asmar-Rios	18 Sep 2020 18:37:14
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:58:11
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:37:14

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:00:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:00:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Sep 2020 21:59:47 23 Sep 2020 21:59:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:41:41
Data point term sent to Coder User entered 'SYMBICORT'	System Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:51 18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information	(b) (4), (b) (6)	23 Sep 2020 21:59:09
User entered 'UPPER RESPIRATORY INFECTION'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '160/4.5'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'ug (ug)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:30:58
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'this was prescribed by PCP on the date provided for an upper respiratory infection ' (Site from DM).	Jacob sekinger (b) (4)	27 Oct 2020 17:58:32
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:03:43
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 18:40:02

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:04:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:04:43
Data point term sent to Coder	System	23 Sep 2020 22:03:53
User entered 'Albuterol'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff 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)	05 Nov 2020 16:05:17
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4)	30 Oct 2020 15:50:21
User entered '90' reason for change: Data Entry Error	Jacob sekinger (b) (4)	30 Oct 2020 15:50:14
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff 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 10:58:58
User entered '2'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	30 Oct 2020 15:50:14
User entered 'puff (PUFF)'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20 Aug 2020'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:57:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:57:23
Data point term sent to Coder	System	19 Oct 2020 18:56:38
User entered 'Gabapentin'	Steven Anderson (b) (4) (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'lumbar pain did not meet AE reporting criteria ' (Site from DM).	Jacob sekinger (b) (4)	20 Nov 2020 15:56:03
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:15:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Lumbar Pain'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '300'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'twice daily (BID)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 18:55:48
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20 Aug 2020'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 18:55:48
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:26:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:20:49

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '18/Aug/2020 09:06'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:26:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '20/Sep/2020 16:19'	System	20 Sep 2020 20:19:22

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:26:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:02:41
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 20:19:22

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '23/Sep/2020 22:02'	System	24 Sep 2020 02:02:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:26:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:54:29
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 02:02:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '02/Oct/2020 12:54'	System	02 Oct 2020 12:54:40

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:26:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:54:40

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'USA-US061-2020-MRNA-1273-P301000001'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:06:43
User entered 'No (N)'	System	18 Aug 2020 13:03:59

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Un-reviewed for Safety.	System	15 Oct 2020 11:47:39
User entered empty.	System	15 Oct 2020 11:47:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 11:47:30
User entered 'OH'	Steven Anderson (b) (4)	02 Oct 2020 17:06:32

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:56

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:19:11
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:42:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:26:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Oct 2020 11:47:39
User entered '4'	System	02 Oct 2020 12:54:40
User entered '3'	System	24 Sep 2020 02:02:52
User entered '2'	System	20 Sep 2020 20:19:22
User entered '1'	System	18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '15/Oct/2020 07:47'	System	15 Oct 2020 11:47:39

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:26:55

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 11:47:39